I hereby certify that this correspondence is being deposited with the United States Postal Service as first-class mail in an envelope addressed to:
Commissioner of Patents and Trademarks, Washington, D.C. 20231
on this 17th day of September, 1991.
By Laura B. Bertman

121*56

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

U.S. PATENT NO. 4,621,638

ISSUED: NOVEMBER 11, 1986

TO: THOMAS A. SILVESTRINI

FOR: HARD ELASTIC SUTURES

Hon. Commissioner of Patents and Trademarks
Washington, D.C. 20231

REQUEST FOR RECONSIDERATION OF DECISION ON APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. §156

Pursuant to 37 C.F.R. 1.750, your Applicant, Pfizer Hospital Products Group, Inc. ("Pfizer") respectfully requests reconsideration of the decision of the Office of the Assistant Commissioner for Patents, dated April 17, 1991, denying any extension of U.S. Patent No. 4,621,638 pursuant to 35 U.S.C. §156.

A four-month extension of time is herewith requested, pursuant to Rule 1.136. The fee of $1150.00 required by Rule 1.17(d) is enclosed. If any further fee is required by this paper, authorization is given to charge Account No. 03-2775.

Attached to this Request for Reconsideration are the following Exhibits:

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1 118 1,150.00 CK

Exhibit I is a copy of the Decision dated April 17, 1991;

Exhibit II is a copy of the Application for Extension filed by Pfizer on February 22, 1991, with attachments;

Exhibit III is a Supplemental Declaration of Gerald H. Schulze, Senior Vice President of Applicant, which attests to the dates of certain relevant events and to the authenticity of the appended Exhibits III(A) to III(J) which are herewith offered into the administrative record; and

Exhibit IV is a copy of a pertinent portion of a House Report during the legislative history of Public Law 90-417, the Drug Price Competition and Patent Term Restoration Act of 1984, which is referenced in the following discussion.

Pfizer is submitting all these exhibits here in order to create a concise and accurate record on which to base the PTO's decision.

DISCUSSION

Pfizer acknowledges that (1) regulatory review of the Deknatel Microflex Ophthalmic Suture did not include submission of an application under Section 515 as part of the testing phase, and (2) the approval phase did not involve either an application or a protocol under Section 515. However, the reason for this is important -- the suture's classification was changed in mid-stream. Regulatory review began under Section 515 but, due to

reclassification, it could not be completed under that Section. As shown in Pfizer's original Application for Extension, and further evidenced by the documents appended to the Supplemental Declaration of Mr. Schulze, the reclassification of Pfizer's suture became effective on July 5, 1990. This was more than two years after Pfizer had commenced human clinical trials under Section 515 (on March 1, 1988), but before an application was filed under that Section. It is clear that a substantial period of the testing phase was carried out under Section 515, before reclassification of the device became effective. Such testing involved the effort and expense (and, of course, the inability to market the device) which is attendant to human clinical trials under Section 515, and that is exactly the delay for which Congress intended compensation by patent term extension.

Awarding relief to Pfizer under the unique circumstances presented here is consistent with the broad remedial purpose of 35 U.S.C. §156. As noted in House Report No. 98-857, Part I, 98th Cong., 2d Sess. 26 (1984), which is attached in part as Exhibit IV:

> The purpose of Title II of the bill is to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval. The incentive

> is the restoration of some of the lost time on patent life while the product is awaiting pre-market approval. Under current law, a patent continues to run while the maker of the product is testing and awaiting approval to market it.
>
> * * *
>
> Those products include: ... medical devices....

Id. at p. 2648.

The same House Report, at page 2677-78, describes the intended regulatory review period for medical devices as follows:

> The regulatory review period for medical devices is the sum of the periods: (1) beginning when human clinical investigations are commenced and ending when an application for approval was initially submitted; and (2) beginning when an application for approval was initially submitted and ending when the application was approved, or beginning when a notice of completion for a product development protocol was initially submitted and ending when the protocol was declared completed.

The relief requested by Pfizer here is consistent with the stated objectives of the legislation. All human clinical investigation under Section 515 was intended to be included, and, Pfizer in fact carried out extensive human clinical trials (over two years) under Section 515.

Although Pfizer recognizes that review solely under Section 510(k) is not a "regulatory review period" within the meaning of the statute, In re Nitinol Medical Technologies, 17 U.S.P.Q. 2d 1492 (Comm. Pat. 1990), in this case extensive review actually occurred under Section 515. Review and approval would have been completed under Section 515 but for a reclassification over which Pfizer had no control. After that reclassification, Pfizer had no choice except to proceed under Section 510. But the injury (delay) that Congress addressed in 35 U.S.C. §156 had already occurred. Accordingly, the Nitinol decision, wherein the review occurred entirely under Section 510(k), is not controlling on the present facts.

For these reasons, reconsideration of the April 17, 1991 decision, and granting of the 409 day extension requested in paragraph 11 of the Application, is requested.

As an alternative basis for relief, Pfizer requests the 409 day extension of patent term based on the following rationale. Specifically, the qualifying testing phase could be considered

terminated as of the effective date of reclassification of Pfizer's device. Specifically, the testing phase should be calculated as beginning on the date when human clinical trials began (March 1, 1988) and ending on the effective date of the suture's reclassification (July 5, 1990), or a period of 856 days. This period corresponds to the period of actual testing under Section 515. Under this rationale, no approval phase is credited towards the extension, since all approval activity necessarily was pursuant to Section 510(k). Thus, the extension period is calculated as follows:

Period = 1/2 (testing phase) + approval phase

Period = 1/2(856) + 0

= 428 days

Again, however, the total period of available extension is limited by operation of Section 156(c)(3) to 409 days. See paragraph 11 of the original Application.

Calculated in this alternative manner, Pfizer is still entitled to the requested 409 day extension of patent term.

Under Section 156, the regulatory review period is based on the sum of the testing phase and the approval phase. The plain meaning of the language of the statute and of the term "sum" does not require either phase to be greater than zero (e.g. the "sum" of 100 and 0 = 100). Pfizer respectfully submits that the PTO erred

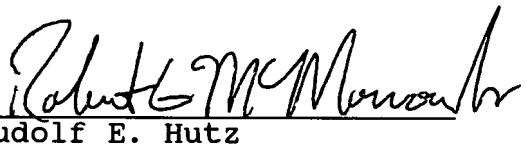
at page 3 of its decision when it suggested that both subsections (i) and (ii) "must be satisfied" i.e. that there must be a positive period under both subsections -- that simply cannot be found in the language.

The facts underlying this request are unique because of the reclassification. Very clearly a regulatory review period began under Section 515, i.e. the clinical investigation on humans. The only issue is when did it end for purpose of defining a set time period for extension. The delay in marketing which Pfizer suffered during the clinical investigation was exactly the period contemplated by Congress. Consequently, Pfizer should be compensated for the delay, and that is all it requests. Section 515 activities ended with the reclassification, and Pfizer believes that this reclassification date can, and should, be the termination of the regulatory review period.

Such relief is entirely consistent with -- and, indeed, required by the legislative intent of Congress reflected in the above quoted portions of the legislative history. If it be assumed that Congress did not specifically consider the unique facts as presented here, the remedial purpose of the statute and the intent of the legislature must govern.

Based on the foregoing, reconsideration and grant of the requested 409 day extension of U.S. Patent 4,621,638 is requested.

Pfizer Hospital
Products Group, Inc.

BY: 

Rudolf E. Hutz
Reg. No. 22,397
Robert G. McMorrow, Jr.
Reg. No. 30,962
CONNOLLY AND HUTZ
1220 Market Building
Wilmington, DE 19899
(302) 658-9141

REH:RGM/lbb
Attachments: 1) Exhibits I-IV
2) Extension of Time Check
3) Power of Attorney

EXHIBIT I

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE COMMISSIONER OF PATENTS AND TRADEMARKS

APR 17 1991

In re Pfizer Hospital Products Group, Inc.	: DECISION ON APPLICATION
U. S. Patent No. 4,621,638	: FOR EXTENSION OF PATENT
	: TERM UNDER 35 U.S.C. § 156

An application for extension of the term of U.S. Patent No. 4,621,638 granted November 11, 1986, which claims a product drawn to a medical device was filed under 35 U.S.C. § 156 in the Patent and Trademark Office (PTO) on February 22, 1991. The medical device claimed by the '638 patent is the Dekantel Microflex Ophthalmic Suture. The application was filed by the patent owner Pfizer Hospital Products Group, Inc. (Pfizer).

The application raises a question of eligibility for patent term extension of a patent claiming a product drawn to a medical device wherein permission to market the device was not approved by the Food and Drug Administration (FDA) under section 515 of the Federal, Food, Drug and Cosmetic Act (FFDCA), but instead was authorized under section 510 (k) of the FFDCA. For the reasons set forth below, the application for extension of the term of the '638 patent is denied.

DISCUSSION

Section 156 (a) (4) of Title 35 permits the term of a patent claiming a medical device which was subject to a "regulatory review period" before its commercial marketing or use to be extended for a period of time equal to a calculated portion of the regulatory review period which occurred after the patent was issued. Under the terms of 35 U.S.C. § 156 (g) (3) (B), the "regulatory review period" for a medical device is limited to a regulatory review which was conducted under section 515 of the FFDCA to the exclusion of a regulatory review conducted under section 510 (k) of the FFDCA. See In re Nitinol Medical Technologies Inc., 17 USPQ2d 1492 (Comm'r Pat. 1990). Accordingly, in order to be eligible for an extension of the term of the patent, the medical device must have been subject to a regulatory review under section 515.

Pfizer asserts that the product (medical device) was subject to regulatory review under section 515 of the FFDCA, noting that the product was originally classified as a Class III device subject to section 515 review and subsequently reclassified by the FDA as a Class II device (application, ¶ 2). The product, a non-absorbable polypropylene suture, was assigned to Class III because it is a "transitional device" which was regulated as a new drug before 1976. Accordingly, as the suture was subject to FDA premarketing approval as a Class III device, an Investigational Device Exemption (IDE) application filed by applicant was approved on March 11, 1988. During the time the human clinical studies were being conducted under the IDE, the FDA, on July 5, 1990, reclassified this type of suture material a Class II device (application, ¶ 2). At the conclusion of the clinical studies a section 510 (k) application was filed with the FDA instead of a section 515 application since the device had been reclassified into Class II (application, ¶ 9). Pfizer states that while final approval was based upon a section 510 (k) submission, prior extensive testing was governed by the provisions of section 515 of the FFDCA (application, ¶ 3).

Pfizer's position that the initial regulatory review of the medical device under section 515 as a Class III device prior to its reclassification by the FDA to a Class II device and subsequent approval under section 510 (k) satisfies the "regulatory review period" requirement of the statute is not tenable. This issue addresses the specific eligibility requirements set by Congress for patent term restoration under section 156 (a) (4).

Section 156 (a) (4) provides:

> (a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent if - ...
>
> > (4) the product has been subject to a regulatory review period before its commercial marketing or use; ... (emphasis added).

The term "regulatory review period" is defined in section 156 (g) (3) which provides:

> (A) In the case of a product which is a medical device, the term means the period described in subparagraph (B) ...
>
> (B) The regulatory review period for a medical device is the sum of - -
>
> > (i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and

(ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515 (f) (5) and ending on the date the protocol was declared completed under section 515 (f) (6) (emphasis added).

The reference to section 515 is a reference to section 515 of the FFDCA. See 35 U.S.C. § 156 (f) (4).

The starting point for statutory interpretation is the plain language of the statute. Unless it is ambiguous, the language Congress chose is conclusive of its meaning absent a clearly stated contrary intention. Burlington Northern R.R. v. Oklahoma Tax Comm'n, 481 U.S. 454, 461 (1987). As noted above, the regulatory review period of a medical device under section 156(g)(3)(B) is the sum of the requirements of subsections (i) and (ii). The plain language of the statute clearly states that both subsections (i) and (ii) must be satisfied. Subsection (i) requires a clinical investigation of the device on humans which ends on the date an application under section 515 is filed. While a clinical investigation was conducted, it did not end with the filing of an application under section 515, but with the filing of a section 510 (k) application. Accordingly, the regulatory review of the medical device which is the subject of the patent term extension application does not satisfy the requirements of subsection (i). Subsection (ii) requires either (1) that an application be filed and completed under section 515 or (2) that a product development protocol be submitted and completed under section 515 (f). Neither of these requirements have been satisfied. Accordingly, the regulatory review of the medical device which is the subject of the patent term extension application does not satisfy the requirements of subsection (ii). Although applicant has undertaken regulatory review for the medical device under section 510(k), the statute does not authorize patent term extension for this type of regulatory review.

Thus, Congress clearly intended that the medical device be approved for marketing under a regulatory review having a testing phase and an approval phase under section 515 of the FFDCA to be eligible for patent term extension.

DECISION

Under the circumstances of this application, for the reasons set forth above, it is held that U.S. Patent No. 4,621,638 is not eligible for extension of the patent term under 35 U.S.C. § 156. The

Dekantel Microflex Ophthalmic Suture has not been subject to a "regulatory review period" within the meaning of 35 U.S.C. § 156 (a) (4) as defined in 35 U.S.C. § 156 (g) (3). Accordingly, the application for extension of the term of U.S. Patent No. 4,621,638 is denied.

PFIZER INC
APR [illegible] 1991
PATENT DEPT

C. E. Van Horn

Charles E. Van Horn
Patent Policy & Programs Administrator
Office of the Assistant Commissioner for Patents

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

Re: Dekantal Microflex
Ophthalmic Suture

FDA Docket No. 91E-0091

cc: John L. LaPierre
Pfizer Inc.
Patent Department
235 East 42nd Street
New York, NY 10017-5755

(For Patent Owner)

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APR 12 1991

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

Re: Dekantel Microflex
Ophthalmic Suture
FDA Docket No. 91E-0091

PFIZER INC
APR 16 1991
PATENT DEPT

Dear Mr. Wilson:

This is in regard to the application for patent term extension for U.S. Patent No. 4,621,638 filed on February 22, 1991, by Pfizer Hospital Products Group. Inc. under 35 USC § 156. The medical device claimed by the '638 patent is the Dekantel Microflex Ophthalmic Suture.

On April 9, 1991, the PTO mailed a letter to the FDA which provided notice under 35 USC § 156 (d) (2) (A) and requested a determination of the applicable review period. Further review of the application and in particular your letter of April 2, 1991, shows, however, that the '638 patent may not be eligible for extension of the patent term under 35 USC §156 because the Dekantel Microflex Ophthalmic Suture was not approved under section 515 of the Federal Food, Drug, and Cosmetic Act, but instead received permission to market under section 510 (k). Accordingly, subject to further review of the application, the April 9, 1991, notice under 35 USC § 156 (d) (2) (A) and request for determination of the applicable review period are hereby rescinded. Until further notice, no action on your part should be taken under 35 USC § 156 (d) (2) (A).

C. E Van Horn

Charles E. Van Horn
Patent Policy & Programs Administrator
Office of the Assistant Commissioner for Patents

cc: John L. LaPierre
Pfizer Inc.
Patent Department, 20th Floor
235 East 42nd Street
New York, NY 10017-5755

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APR 9 1991

PFIZER INC
APR 10 1991
PATENT DEPT

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

RE: Dekantel Microflex
Ophthalmic Suture
FDA Docket NO. 91E-0091

Dear Mr. Wilson:

Transmitted herewith is a copy of the application for Patent Term Extension of U.S. Patent No. 4,621,638 issued November 11, 1986. The application was filed on February 22, 1991, under Title II of Public Law 98-417, the Drug Price Competition and Patent Term Restoration Act of 1984.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 USC § 156(d)(2)(A).

703 557-3054

C. E. Van Horn

Charles E. Van Horn
Patent Policy and Programs Administrator
Office of the Assistant Commissioner for Patents

PLEASE SEND TO:

PCR	AJS
LCA	MJP
KXD	EOS
MXD	RFS
GFF	RCT
[illegible]	GCB
[illegible]G	RKB
GH	JTL
GNJ	JMM
HRJ	ADO
JLL	RWA
	TCN

cc: John L. LaPierre
Pfizer Inc.
Patent Department, 20th Floor
235 East 42nd Street
New York, N.Y. 10017-5755

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 1991

Re: Dekantel Microflex
Ophthalmic Suture
Docket No. 91E-0091

Charles E. Van Horn
Patent Policy and Projects Administrator
Office of the Assistant Commissioner for Patents
Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, D.C. 20231

PFIZER INC
APR 05 1991
PATENT DEPT

Dear Mr. Van Horn:

This is in regard to the application for patent term extension for U. S. Patent No. 4,621,638 filed by Pfizer Hospital Products Group, Inc., under 35 U.S.C 156. The medical device claimed by the patent is the Dekantel Microflex Ophthalmic Suture.

A review of the Food and Drug Administration's official records does not confirm that the Dekantel Microflex Ophthalmic Suture was subject to a regulatory review period as it is defined in 35 U.S.C. 156. For medical devices, section 156(g)(3) limits the meaning of the term "regulatory review period," to periods of time related to product approvals under section 515 of the Federal Food, Drug, and Cosmetic Act (FFDCA). The Dekantel Microflex Ophthalmic Suture was not approved under section 515, but instead received permission to market under section 510(k)of the FFDCA.

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. 156(d)(2)(A), we will then determine the applicable regulatory review period, publish that determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Ronald L. Wilson

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

CC: John L. LaPierre
Pfizer Inc.
Patent Department, 20th Floor
235 East 42nd Street
New York, NY 10017-5755

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

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MAR 07 1991

PFIZER INC
MAR 11 1991
PATENT DEPT

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

PC# 6794 A

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 4,621,638 issued November 11, 1986, was filed on February 22, 1991, under 35 U.S.C. 156.

The assistance of your Office is requested in determining whether the product identified in the application has been subject to a regulatory review period within the meaning of 35 USC § 156(g) before its commercial marketing or use. Since a determination has not been made whether the patent in question claims a product which is subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 USC § 156(d)(2)(A).

Our review of the application indicates that the product was not approved under section 515, but instead received permission to market under section 510(k) of the FFDCA. Accordingly, the subject patent may not be eligible for extension of the patent term under 35 USC § 156.

C. E. Van Horn

Charles E. Van Horn
Patent Policy & Programs Administrator
Office of the Assistant Commissioner for Patents

cc: John L. LaPierre
Pfizer Inc.
Patent Department, 20th Floor
235 East 42nd Street
New York, NY 10017-5755

Ex II

PATENT

PC 6794A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE: U.S. PATENT NO. 4,621,638:
ISSUED: NOVEMBER 11, 1986 :
TO: THOMAS A. SILVESTRINI :
FOR: HARD ELASTIC SUTURES :

Hon. Commissioner of Patents and Trademarks
Box Patent Extension
Washington, D.C. 20231

Sir:

APPLICATION FOR EXTENSION OF THE TERM OF UNITED STATES PATENT NO. 4,621,638 UNDER 35 U.S.C. 156

Your applicant, **PFIZER HOSPITAL PRODUCTS GROUP, INC.**, a corporation organized and existing under the laws of the State of Delaware and having a place of business at **235 East 42nd Street, New York, New York,** represents that it is the owner of the entire right, title and interest in and to Letters Patent of the United States No. 4,621,638, granted to **THOMAS A. SILVESTRINI** on the 11th day of November, 1986, for HARD ELASTIC SUTURES, by virtue of an assignment recorded in the United States Patent and Trademark Office on July 15, 1985 at Reel 4430, Frame 792. Pursuant to the provisions of 35 U.S.C. 156, your applicant hereby applies for an extension of the term of said United States patent of 409 days, based upon the materials set forth herein and in the accompanying papers. In the materials which follow, paragraph numbers correspond where applicable to the paragraph numbers set forth in 37 C.F.R. 1.740(a).

(1) The approved product is a Non-Absorbable Polypropylene Surgical Suture for use in ophthalmic surgery.

(2) The suture was subject to regulatory review under Section 515 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360(e)). The product was originally classified as a Class III device subject to the Section 515 review. Subsequently, the device was reclassified as a transitional device and reclassified into Class II in accordance with the

Food and Drug Administration, Notice of Reclassification, Docket Number 88P-0173, effective July 5, 1990.

(3) The Food and Drug Administration granted permission for commercial marketing or use of the suture on December 24, 1990. A copy of the Food and Drug Administration letter of approval is attached hereto as EXHIBIT A. It should here be noted that while final approval was based upon a Section 510(k) submission, prior extensive testing was governed by the provisions of Section 515 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360(e)).

(4) This application is being submitted within the sixty day period permitted for its submission pursuant to 37 C.F.R. 1.720(f). The last day on which this application could be submitted is February 22, 1991.

(5) The patent for which an extension is being sought is identified as follows:

Inventor: **THOMAS A. SILVESTRINI**
Patent No.: **4,621,638**
Title: **HARD ELASTIC SUTURES**
Issued: **NOVEMBER 11, 1986**
Expires: **NOVEMBER 11, 2003**

(6) A copy of United States Patent No. 4,621,638, the patent for which an extension is being sought, is attached hereto as EXHIBIT B.

(7) No disclaimer, certificate of correction or reexamination certificate issued for United States Patent No. 4,621,638. The maintenance fee has been paid for United States Patent No. 4,621,638. Attached hereto as EXHIBIT C is a copy of receipt of Maintenance Fee Statement.

(8) United States Patent No. 4,621,638 claims the approved product. The manner in which each applicable patent claim reads on the approved product is as follows.

Claim 1 of U.S. 4,621,638 claims a surgical suture comprising at least one sterile hard elastic filament of a body-compatible polymer. The approved product is a suture having a sterile hard elastic filament of a body-compatible polymer.

Claim 2 of U.S. 4,621,638 claims a suture which is a monofilament. The approved suture is a monofilament.

Claim 3 of U.S. 4,621,638 claims a suture wherein the polymer is polypropylene. The approved suture polymer is polypropylene.

Claim 4 of U.S. 4,621,638 claims a monofilament having a diameter in the 0.020-0.039 mm range. The approved suture, which is a 9-0 suture, has a diameter in the range of from 0.030-0.039 mm.

Claim 6 of U.S. 4,621,638 claims a polypropylene suture with the Young's modulus of the filament being in a range of 0.25-5.0 g/denier. The approved suture has a Young's modulus in this range.

Claim 12 of U.S. 4,621,638 claims a needled surgical suture having at least one sterile hard elastic filament of a body-compatible polymer attached to a sterile surgical needle. The approved suture is as aforesaid in respect to claim 1 and the suture is attached to a sterile surgical needle.

Claim 13 of U.S. 4,621,638 claims a needled surgical suture wherein the polymer is polypropylene. The approved suture polymer is polypropylene.

Claims 14 and 15 of U.S. 4,621,638 claim a surgical suture package having a sterile enclosure containing a sterile needled surgical suture having at least one hard elastic filament of a body-compatible polymer and wherein the polymer is polypropylene. The approved suture is as aforesaid in respect to claim 1 and the suture is attached to a sterile surgical needle and packaged in a sterile enclosure. The approved suture is polypropylene.

Claim 16 of U.S. 4,621,638 claims a method of suturing by stitching with at least one sterile hard elastic filament made of a body-compatible polymer. The approved product is a suture for use in suturing. The suture includes a hard elastic filament made of a body-compatible polymer.

Claims 17-19 of U.S. 4,621,638 claim the method wherein the polymer used is polypropylene, the filament ranges in

diameter from 0.020-0.039 mm and the filament has a Young's modulus of 0.25-5.0 g/denier. The approved suture for use in suturing by stitching includes these characteristics as aforesaid in respect to claims 3, 4 and 6.

Claim 20 of U.S. 4,621,638 claims a method wherein the stitching is performed in corneal surgery. The approved product is a suture for use in ophthalmic surgery.

(9) The relevant dates and information pursuant to 35 U.S.C. 156(g) in order to permit the Secretary of Health and Human Services to determine the applicable regulatory review period are as follows.

(a) The IDE application was conditionally approved February 5, 1988. The IDE number assigned was G880005. Final IDE approval was given March 11, 1988.

Human clinical investigation involving the device began March 1, 1988.

(b) The completed final product report was submitted August 21, 1990. A Section 510(k) application was filed on August 21, 1990 and the application was give identification number K903643. The Section 510(k) was filed instead of a Section 515 since the device was reclassified as a transitional device and reclassified into Class II as aforestated in Paragraph (2) herein.

(c) On November 27, 1990, the Food and Drug Administration declared that the application was completed.

(10) A brief description of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities is attached hereto as EXHIBIT D.

(11) Applicant is of the opinion that United States Patent No. 4,621,638 is eligible for an extension under 35 U.S.C. 156 and the length of extension claimed is 409 days. The length of extension of the term of U.S. Patent No. 4,621,638 of 409 days claimed by applicant was determined according to the provisions of 35 U.S.C. 156(c) and 156(g). The period of extension is calculated according to the formula

Period = ½ (Testing Phase) + Approval Phase

wherein the Testing Phase herein equals the number of days between the human clinical evaluation and submission of the final report (March 1, 1988 through August 21, 1990) or 903 days and the Approval Phase equals the number of days from the submission of the completed report to the date of product approval (August 21, 1990 through December 24, 1990) or 125 days. Thus,

Period = ½ (903) + 125
= 452 + 125
= 577 days

However, the exception of 35 U.S.C. 156(c)(3) operates to limit the term of extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (December 24, 1990) when added to the period of extension calculated above (577 days) cannot exceed fourteen (14) years. The period of extension is thus limited to December 24, 2004 by operation of 35 U.S.C. 156(c)(3). Since the patent term of seventeen (17) years would expire November 11, 2003, the period of extension is the number of days to extend the term of the patent to December 24, 2004 or four hundred and nine (409) days.

(12) Applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the four hundred and nine day extension being sought to the term of United States Patent No. 4,621,638.

application for extension is to be charged to Deposit Account No. 16-1445, as authorized in the enclosed transmittal letter.

(14) Please address all inquires and correspondence relating to this application for patent term extension to:

John L. LaPierre
Pfizer Inc.
Patent Department, 20th Floor
235 East 42nd Street
New York, NY 10017-5755
(212) 573-1594

(15) A duplicate of these application papers, certified as such, is enclosed herewith.

(16) A declaration pursuant to 37 C.F.R. 1.740(a)(17) and 1.740(b) is enclosed herewith.

Respectfully submitted,

PFIZER HOSPITAL PRODUCTS GROUP, INC.

Dated: February 22, 1991 by: _____
G. SCHULZE

Pfizer Inc.
Patent Department, 20th Floor
235 E. 42nd Street
New York, NY 10017-5755
(212) 573-1594

(jl)291189.JLL

PATENT

PC 6794A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE: U.S. PATENT NO. 4,621,638 :

ISSUED: NOVEMBER 11, 1986 :

TO: THOMAS A. SILVESTRINI :

FOR: HARD ELASTIC SUTURES :

Hon. Commissioner of Patents and Trademarks
Box Patent Extension
Washington, D.C. 20231

Sir:

DECLARATION ACCOMPANYING APPLICATION OF PFIZER HOSPITAL PRODUCTS GROUP, INC. FOR EXTENSION OF THE TERM OF U.S. PATENT NO. 4,621,638 UNDER 35 U.S.C. 156

I, Gerald H. Schulze, declare as follows:

THAT I am a Sr. Vice President of **PFIZER HOSPITAL PRODUCTS GROUP, INC.**, and that I am authorized to obligate said **PFIZER HOSPITAL PRODUCTS GROUP, INC.**;

THAT I have reviewed and I understand the contents of the application of **PFIZER HOSPITAL PRODUCTS GROUP, INC.**, dated February 22, 1991, which is being submitted herewith for extension of the term of United States Patent No. 4,621,638 under 35 U.S.C. 156;

THAT I believe that United States Patent No. 4,621,638 is subject to extension pursuant to 35 U.S.C. 156 and 37 C.F.R. 1.710;

THAT I believe that the extension of term of United States Patent No. 4,621,638 of 409 days which is being claimed by **PFIZER HOSPITAL PRODUCTS GROUP, INC.** is justified under 35 U.S.C. 156 and the applicable regulations; and

THAT I believe that the patent for which extension is being sought meets the conditions for extension of the term of a patent as set forth in 35 U.S.C. 156 and 37 C.F.R. 1.720.

I declare further that all statements made herein of my own knowledge are true and that all statements made on

information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application being submitted herewith or any extension of patent term granted hereon.

Signed this 22nd day of February, 1991 at New York, New York.

(jl)291187.jll

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

EXHIBIT A

DEC 24 1990

Mr. Harry Savard
Manager, Regulatory Affairs
Deknatel Division
Pfizer Hospital Products Group, Inc.
600 Airport Road
P.O. Box 2980
Fall River, Massachusetts 02722-2980

Re: K903643
Deknatel® Microflex™ Ophthalmic
Dyed Polypropylene Suture
Dated: October 30, 1990
Received: October 31, 1990

Dear Mr. Savard:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices that were regulated as transitional devices and that have been reclassified into class II. Notice of this reclassification will be announced in a future Federal Register notice. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. The Deknatel® Microflex™ Ophthalmic Polypropylene Nonabsorbable Surgical Suture is indicated for use in ophthalmic surgery only.

2. This device may not be manufactured from any material other than a long chain polyolefin polymer known as polypropylene. In addition, you must maintain documentation at your premises regarding vendor certification for raw or semiprocessed source material, all manufacturing and quality control release procedures, and validation of sterilization procedures used in the manufacture of the Polypropylene surgical suture. Any deviation of the source material or processing as described in this 510(k) notification must be submitted to the Food and Drug Administration (FDA) in a new premarket notification at least 90 days prior to implementation of the proposed change(s).

The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibition against misbranding and adulteration.

Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a reclassified transitional device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

for David L. West, Ph.D.
Deputy Director
Office of Device Evaluation
Center for Devices and
Radiological Health

EXHIBIT B

United States Patent [19]

Silvestrini

[11] Patent Number: 4,621,638

[45] Date of Patent: Nov. 11, 1986

[54] HARD ELASTIC SUTURES

[75] Inventor: Thomas A. Silvestrini, East Lyme, Conn.

[73] Assignee: Pfizer Hospital Products Group, Inc., New York, N.Y.

[21] Appl. No.: 754,716

[22] Filed: Jul. 15, 1985

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 635,790, Jul. 30, 1984, abandoned.

[51] Int. Cl.[4] A61B 17/00

[52] U.S. Cl. ..... 128/335.5; 264/176.F 264/178 F

[58] Field of Search ..... 128/335.5; 264/176 F, 264/178 F

[56] References Cited

U.S. PATENT DOCUMENTS

3,359,983	12/1967	Northey	128/335.5
3,454,011	7/1969	Wagner	128/335.5
3,565,077	2/1971	Glick	128/335.5
3,630,205	12/1971	Listner	128/335.5

Primary Examiner—Jacqueline V. Howard

Attorney, Agent, or Firm—Charles J. Knuth; Peter C. Richardson; Gezina Holtrust

[57] ABSTRACT

A surgical suture made of a polymer filament having the "hard" elastic properties of reversible elasticity and retention of diameter on stretching.

20 Claims, 3 Drawing Figures

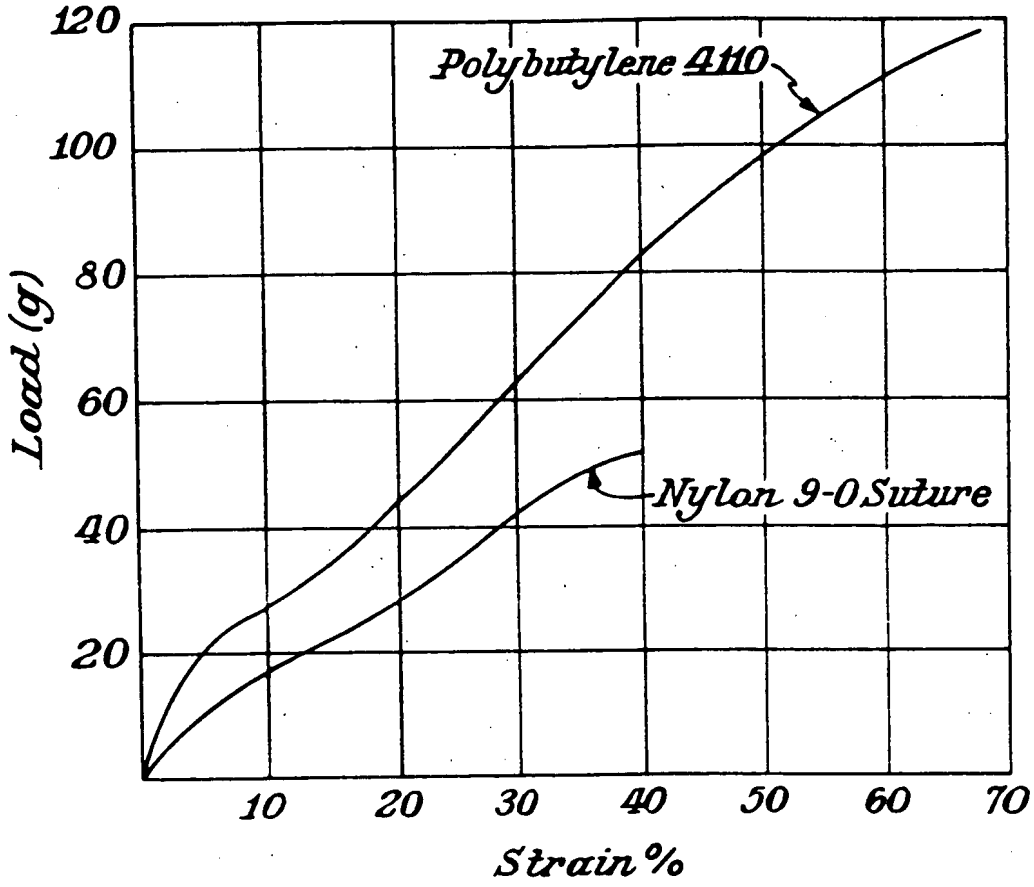

120
100
80
60
40
20
Load (g)
Polybutylene 4110
Nylon 9-0 Suture
10
20
30
40
50
60
70
Strain %

Fig. 1.

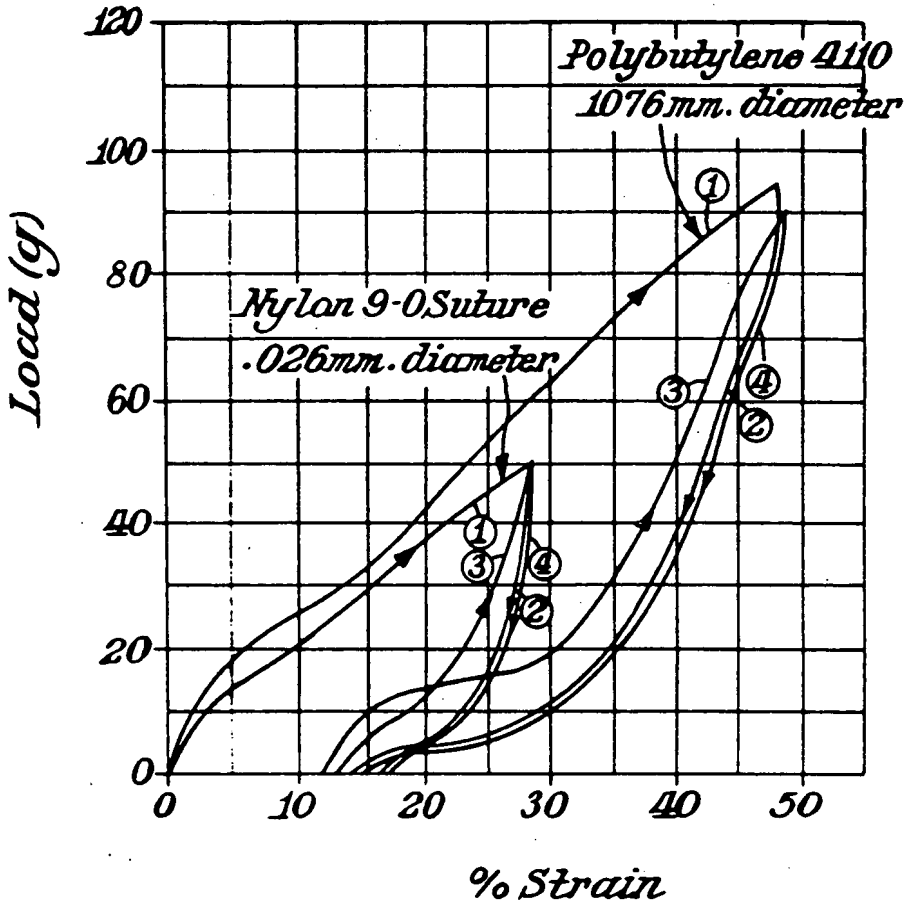

Polybutylene 4110
1076mm. diameter
Mylon 9-0Suture
.026mm. diameter
Load (g)
% Strain
120
100
80
60
40
20
0
0
10
20
30
40
50
1
2
3
4

Fig. 2.

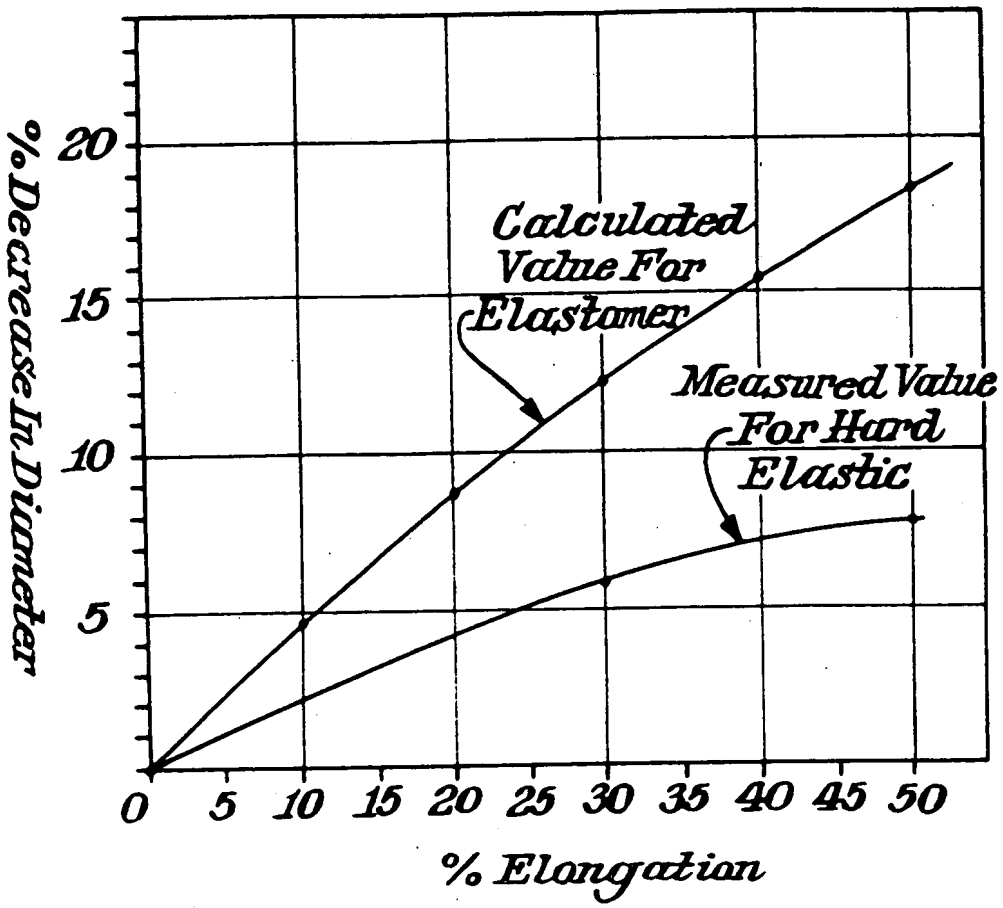

% Decrease In Diameter
20
15
10
5
0
5
10
15
20
25
30
35
40
45
50
% Elongation
Calculated Value For Elastomer
Measured Value For Hard Elastic

Fig. 3.

HARD ELASTIC SUTURES

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of application Ser. No. 635,790, filed July 30, 1984, now abandoned.

BACKGROUND OF THE INVENTION

This invention relates to the field of surgical sutures, more particularly to the field of fine sutures for corneal surgery.

Opthalmic sutures are necessarily of fine gauge, and so must be made of strong filaments. However, if the suture is too fine, even though strong, the suture can cut through and damage the corneal tissue. If too large, the suture will not allow burying the suture knot in the sclera and results in irritation and discomfort. Conventional ophthalmic sutures are generally made of nylon filaments. These materials produce sutures that perform reasonably well, but still have deficiencies. In particular, they are not elastic enough to expand and contract adequately with tissue swelling due to edema. This can result in damage and poor wound healing. Therefore, it would be advantageous to have an elastic opthalmic suture. However, most elastic filaments shrink in diameter as they elongate. This makes them unsuitable for use as opthalmic sutures because, as the wound swells and tension in the suture increases, the suture diameter decreases. This reduced diameter coupled with the increased tension make it more likely that the suture will cut through and damage the delicate tissue.

Thus, the ideal suture for corneal tissue would be of high strength to allow use of fine size, reversibly elastic to accommodate edema, and capable of substantially maintaining its initial diameter when elongated to minimize cutting through tissue.

U.S. Pat. No. 3,630,205 discloses flexible polypropylene sutures. However, the polypropylene used is not a "hard" elastic material as defined hereafter.

SUMMARY OF THE INVENTION

According to the invention, a suture is made of hard elastic filaments of a body-compatible polymer.

The term "hard elastic" is used by R. G. Quinn et al., J. Macromol. Sci. Phys., B5(4), 721-738 (Dec., 1971) with reference to fibers prepared from semicrystalline polymers having long range mechanical elasticity, i.e. a high degree of length recovery from large extensions, specifically at least about 90% recovery on 30% extension, a marked reduction in apparent density on stretching, and generation of very large amounts of accessible volume and surface area on stretching. The large, mainly reversible reduction in apparent density on stretching sharply distinguishes the hard elastic filament from elastic filaments. This reduction in density results in little or no decrease in filament diameter on stretching.

In accordance with the invention, a hard elastic filament is one which (1) shows substantially less decrease in filament diameter on stretching when compared to conventional elastomeric filament, (2) is at least about 90% reversibly elastic on elongation of up to 30% subsequent to one elongation and relaxation cycle, and (3) exhibits characteristic elasticity in which the slope of the stress strain curve of the filament changes without plastic yield deformation.

As to (2) above, the 90% reversible elasticity on 30% elongation is found in elongation and relaxation cycles subsequent to the first elongation and relaxation cycle.

The hard elastic filament according to the invention is made from a polymer having a special crystalline morphology which is a result of specific high stress spinning conditions described in the art cited hereafter.

Polymers capable of forming hard elastic filaments under high stress spinning conditions are polyolefins such as isotactic polybutylene (also known as poly(butene-1)), isotatic polypropylene(PP) and polyethylene(PE), and mixtures of isotactic and non-isotactic polyolefins.

Isotactic copolymers of olefins such as butene-1/ethylene copolymers and blends of isotactic homo- and copolymers of olefins such as PP/PE blends are suitable as well. Examples of other suitable polymers are polyoxymethylene, polyisobutylene oxide, polyester and nylon. All of the above polymers are suitable for use as nonabsorbable sutures.

Other suitable polymers are polycaprolactone, polycaprolactam, polyhydroxybutyric acid(PHB), polyglycolic acid(PGA) and polylactic acid(PLA), and blends thereof such as blends of PGA and PLA, and PHB and PGA. These polymers are slowly absorbable in the body and may therefore be made into absorbable sutures.

The manufacture of hard elastic filaments is described in the art, for instance in U.S. Pat. Nos. 4,006,208 (polyisobutylene oxide), 3,840,510 (butene-1 polymers), 3,686,385 (poly(butene-1)), 3,549,743 (PP), 3,513,110 (polyester and polycarbonamide), 3,432,590 (PP), 3,323,190 (PP), 3,330,897 (polyolefines) and 3,256,258 (PP), the disclosures of which patents are herewith incorporated by reference.

Fine gauge sutures can be made of hard elastic filaments in either monofilament or multifilament form. While fine gauge hard elastic monofilament sutures are especially suitable for opthalmic use, larger diameter monofilament and multifilament sutures are useful in general surgery.

It is the purpose of this invention to provide a suture which is reversibly elastic to stretch on wound swelling, but does not significantly decrease in diameter during that elongation. It is another purpose to provide such a suture as a fine gauge monofilament suitable for opthalmic use.

DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. 1 presents stress-strain curves of a nylon 9-0 suture (0.036 mm. diameter) and a polybutylene filament according to the invention.

FIG. 2 presents hysteresis curves of the nylon suture and the polybutylene filament.

FIG. 3 presents curves comparing the % decrease in diameter vs. % elongation of a conventional elastomeric filament with a hard elastic filament of the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Continuous filaments with hard elastic properties can be made from a number of highly crystalline polymers that are also suitable for use as sutures in the human body, as described above. Filaments made of polybutyl-

ene and PP/PE blends are advantageous since hard elastic properties are reliably obtained on proper processing of these polymers. Isotactic PP is advantageously used because of combination of high strength and good eye-compatibility. A suitable grade of crystalline isotactic PP is sold by Hercules Inc. under the trademark "Profax". Shell Polybutylene 4110, 0400, 0300, 0200, 8640, 8240 and 8010 are suitable butylene and butylene-ethylene polymers available from Shell Chemical Company. Exxon polypropylene (DMF #492) is a suitable mixture of isotactic and non-isotactic polypropylene available from the Exxon Corporation.

A conventional elastomeric filament has a constant density and volume during stretching so that the diameter of the filament must decrease during stretching. Such decrease can be accurately calculated. The results of such calculations are set out in FIG. 3 and below as follows:

% Elongation	% Decrease in Diameter
0	0
10	4.7
20	8.7
30	12.3
40	15.5
50	18.4

The measured decrease in diameter for a hard elastic polypropylene filament of size 9-0 (0.036 mm) of the invention is set out in FIG. 3. As shown in FIG. 3, the measured decrease in diameter of the hard elastic filament is substantially less than the calculated diameter decrease of the conventional elastomeric filament. Generally, the % diameter decrease of a hard-elastic filament of the invention ranges from 0 to 10% on 50% stretching, and from 0 to about 8% in the case of the hard elastic filament of FIG. 3.

According to one embodiment of the invention, the hard elastic filament shows little or no decrease in diameter on stretching, e.g. about 3 to 4% diameter decrease on stretching to 25%, 30% or 50% of the original length.

According to a preferred embodiment of the invention, on 100% extension the filament has at least about 80% instantaneous recovery and 10% remaining recovery within a few minutes.

Generally, a monofilament suture having a Young's modulus of about 0.25 g/d to about 5.0 g/d is suitable for use in the invention, although this range is not critical to the invention. When softer hard elastic filaments are desired, the filament may be subjected to a final heat treatment step while the filament is in a stretched condition. For example, H. D. Noether et al., Textile Res. J., 46, 467–478 (1976) report production of hard elastic filaments with much reduced Young's modulus by heat treatment at 130° C. and 100% extension for 30 minutes. Materials of high elasticity in the 1–10 g/d modulus range and having tenacities between 1 and 4 g/d are formed.

The invention is not limited to hard elastic filaments made by any particular method. In general, hard elastic filaments may be produced from suitably crystalline polymers by spinning under high stress conditions as known to those skilled in the art. The high stress spinning conditions, particularly the melt temperature and draw ratio, depend on the particular polymer material being used. For instance, polybutene-1 generally requires spinning at melt temperatures of about 190° to 300° C. and at draw ratios of about 10 to about 5,000, preferably 100 to 400. Polybutylene oxide requires a melt temperature of from about 175° C. up to the decomposition temperature of polybutylene oxide and a draw ratio of about 50 to 1000, preferably 300 to 500. Polypropylene requires generally a melt temperature of about 160° to 260° C. and draw ratios of about 60 to 300. Temperatures of above about 60° C. and above about 100° C. are used for polyamides and polyesters, respectively, with draw ratios of about 200 to 4,000.

After suitable hard elastic filaments have been produced, they must be converted into sutures. If the suture is not to be a monofilament, a plurality of filaments may be combined, as by braiding, into a multifilament braid. The monofilament or multifilament strand is cut into desired lengths and sterilized. Needles may be attached. The sutures, with or without needles, are packaged in sterile enclosures to maintain sterility until time of use. Alternatively, sterilization may take place after packaging. Methods for carrying out these conversion steps are well known in the art, and the invention is not limited to any particular combination of them.

Monofilament hard elastic sutures in 9-0 (0.030–0.39 mm in diameter) and 10-0 (0.020–0.029 mm in diameter) size are especially useful for ophthalmic surgery. However, both mono- and multifilament hard elastic sutures can be made in a wide range of sizes suitable for many surgical procedures. The unusual elastic properties of the sutures of the invention will be beneficial to surgery requiring difficult anastomosis such as bowel and blood vessel anastomosis, and microsurgery to reconnect nerves. The sutures of the invention are also uniquely suitable in plastic and reconstructive surgery generally using a size range of about 4-0 (0.15–0.199 mm in diameter) to 7-0 (0.05–0.069 mm in diameter), and preferably 5-0(0.10–0.149 mm in diameter). Also, sutures according to this invention can be made of any body-compatible polymer that can be sterilized, has the required strength and can exhibit the property of hard elasticity. The sutures of the invention can be dyed with dyes conventionally utilized in corneal surgery such as copper phthalocyanine.

The following example illustrates the invention.

EXAMPLE

Polybutylene (Shell Polybutylene 4110) was melt-spun into a multifilament yarn at a spin draw ration of 126. Table 1 sets out the physical properties of the polybutylene (PB) used. Individual filaments in the yarn measured 0.076 mm. in diameter. A hard elastic PB filament was formed having a stress-strain curve and a cyclic load-strain hysteresis curve characteristic of hard elastic filaments as shown in FIGS. 1 and 2.

The change in the slope of the curve for the PB filament at about 6% strain in FIG. 1 does not represent a yield point where deformation is irreversible. The PB filament broke at about 68% strain and showed good recovery up to 50% strain.

The curve for the nylon suture in FIG. 1 has two yield points at about 4% and about 35% strain. The nylon suture thus has two yield points before 50% strain whereas the PB filament has none. The nylon suture broke at 50% strain and showed no recovery after 35% strain.

The initial elastic recovery ratio of the PB filament after one elongation (1) to 50% of the original length and relaxation (2) was about 75%. FIG. 2 also presents

the hysteresis curve on second elongation (3) and relaxation (4). Recovery ratios increased to about 96% after elimination of residual set in the first elongation relaxation cycle. The final reversible elongation was at least 30% with 96% recovery.

FIG. 2 shows the hysteresis curves of the nylon suture after one elongation (1) relaxation (2) cycle and a second elongation (3) relaxation (4) cycle. The nylon suture has 60% elastic recovery after the first cycle to 30% strain, and 78% elastic recovery on subsequent cycles. The final reversible elongation was only 15% with 78% recovery.

TABLE 1

	ASTM Test	English		Metric	
	Method	Unit	Value	Unit	Value
General properties					
Melt index	D 1238	—	—	g/10 min	0.4
Density	D 1505	lb/ft^3	57.1	g/cm^3	0.915
Mechanical properties					
Tensile strength at yield	D 638	psi	2400	kg/cm^2	170
Tensile strength at break	D 638	psi	4800	kg/cm^2	340
Elongation at break	D 638	%	280	%	280
Modulus of elasticity	D 638	psi	38,000	kg/cm^2	2700
Thermal Properties					
Melting point range	DTA	°F.	225–259	°C.	124–126
Softening point vicat	D 1525	°F.	235	°C.	113

I claim:

1. A surgical suture comprising at least one sterile hard elastic filament of a body-compatible polymer.

2. A surgical suture as in claim 1 wherein the suture is a monofilament.

3. A surgical suture as in claim 2 wherein the polymer is selected from the group consisting of polypropylene, poly(butene-1), ethylene-butylene copolymer, nylon and polyester.

4. A surgical suture as in claim 3 wherein the monofilament is 0.020–0.039 mm in diameter.

5. A surgical suture as in claim 2 wherein the monofilament is 0.05–0.199 mm in diameter.

6. A surgical suture as in claim 2 wherein the polymer is polypropylene or poly(butene-1) and the Young's modulus of the filament is 0.25–5.0 g/denier.

7. A surgical suture as in claim 1 wherein the suture is a multifilament suture.

8. A surgical suture as in claim 7 wherein the polymer is selected from the group consisting of polypropylene, poly(butene-1), ethylene-butylene copolymer, nylon and polyester.

9. A surgical suture as in claim 8 wherein the multifilament suture is a braided suture.

10. A surgical suture as in claim 1 wherein the polymer is a body-absorbable polymer.

11. A surgical suture as in claim 10 wherein the polymer is selcted from the group consisting of polyhydroxybutyric acid, polyglycolic acid and polylactic acid.

12. A needled surgical suture comprising at least one sterile hard elastic filament of a body-compatible polymer attached to a sterile surgical needle.

13. A needled surgical suture as in claim 12 wherein the polymer is polypropylene or poly(butene-1).

14. A surgical suture package comprising a sterile enclosure containing a sterile needled surgical suture, the suture comprising at least one hard elastic filament of a body-compatible polymer.

15. A surgical suture package as in claim 14 wherein the polymer is polypropylene or poly(butene-1).

16. A method of suturing by stitching with at least one sterile hard elastic filament made of a body-compatible polymer.

17. A method as in claim 16 wherein the polymer is selected from the group consisting of polypropylene, poly(butene-1), ethylene-butylene copolymer, nylon and polyester.

18. A method as in claim 17 wherein the polymer is polypropylene and the filament is 0.020–0.039 mm. in diameter.

19. A method as in claim 17 wherein the filament has a Young's modlus of 0.25–5.0 g/denier.

20. A method as in claim 16 wherein said stitching is performed in corneal surgery.

* * * * *

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D. C. 20231

PAYOR NUMBER
000127

EXHIBIT C

PFIZER INC.
APR 05 1990
PATENT DEP.

BERNICE CUMMINGS
PFIZER INC.
PATENT DEPARTMENT - 20TH FLOOR
235 EAST 42ND STREET
NEW YORK, NY 10017

DATE MAILED
04/02/90

097260

MAINTENANCE FEE STATEMENT

The data shown below is from the records of the Patent and Trademark Office. If the maintenance fees and any necessary surcharges have been timely paid for the patents listed below, the notation "PAID" will appear in column 10, "status" below.

If a maintenance fee payment is defective, the reason is indicated by code in column 10, "status" below. An explanation of the codes appears on the reverse of the Maintenance Fee Statement. TIMELY CORRECTION IS REQUIRED IN ORDER TO AVOID EXPIRATION OF THE PATENT. NOTE 37 CFR 1.377. THE PAYMENT(S) WILL BE ENTERED UPON RECEIPT OF ACCEPTABLE CORRECTION. IF PAYMENT OR CORRECTION IS SUBMITTED DURING THE GRACE PERIOD, A SURCHARGE IS ALSO REQUIRED. NOTE 37 CFR 1.20(k) and (l).

If the statement of small entity status is defective the reason is indicated below in column 10 for the related patent number. THE STATEMENT OF SMALL ENTITY STATUS WILL BE ENTERED UPON RECEIPT OF ACCEPTABLE CORRECTION.

ITM NBR	PATENT NUMBER	FEE CDE	FEE AMOUNT	SUR CHARGE	SERIAL NUMBER	PATENT DATE	FILE DATE	PAY YR	SML ENT	STAT
1	4,620,533	173	490	----	06/776,259	11/04/86	09/16/85	04	NO	PAID
2	4,621,630	173	490	----	06/485,541	11/11/86	04/15/83	04	NO	PAID
(3)	4,621,638	173	490	----	06/754,716	11/11/86	07/15/85	04	NO	PAID
4	4,624,256	173	490	----	06/774,636	11/25/86	09/11/85	04	NO	PAID
5	4,631,082	173	490	----	06/703,352	12/23/86	02/20/85	04	NO	PAID

If the "status" column for a patent number listed above does not indicate "PAID" a code or an asterisk (*) will appear in the "status" column. Where an asterisk (*) appears, the codes are set out below by the related item number. An explanation of the codes indicated in the "status" column and as set out below by the related item number appears on the reverse of the maintenance fee statement.

ITM NBR	ATTY DKT NUMBER
1	PC(HO) 6926
2	DPCH06674
3	PC 6794A
4	PC 6873
5	PC 6896

DIRECT THE RESPONSE TOGETHER WITH PART B OF THIS NOTICE, AND ANY QUESTIONS ABOUT THIS NOTICE TO: COMMISSIONER OF PATENTS AND TRADEMARKS, BOX M. FEE, WASHINGTON, DC 20231

PTO/-439 (REV 1-85)

PART A

EXHIBIT D

CHRONOLOGY OF NON-ABSORBABLE POLYPROPYLENE SURGICAL SUTURE CLINICAL INVESTIGATION

December 23, 1987	FDA Telephone Contact Report: Feasibility Study Request
January 11, 1988	Submission of Clinical Feasibility Studies
January 12, 1988	Submission Received at FDA and Assigned IDE NO. G880005
February 5, 1988	Conditional Approval of IDE Application Request for Additional Information
February 25, 1988	Submission of IDE Supplement with Additional Information
March 3, 1988	Human Clinical Studies Began
March 11, 1988	Approval of IDE Application
August 5, 1988	6-Month Report-Investigator List
September 29, 1988	FDA Meeting Report: Suggested that Feasibility IDE Study be Supplemented to Increase Patient Numbers
October 19, 1988	FDA Meeting Report: Summarized Ophthalmic Study and USP vs. Elastic Suture Specs
January 9, 1989	IDE Supplement for Investigational Plan Changes
February 6, 1989	IDE Supplement Approval
February 28, 1989	Yearly Progress Report
August 31, 1989	6-Month Report-Investigator List
May 1, 1990	Human Clinical Studies Completed
May 2, 1990	Annual Progress Report

EXHIBIT D - (Continued)

June 7, 1990	FDA Acknowledgement of May 2, 1990 Report
August 21, 1990	Final Report IDE G880005
September 10, 1990	Final Report - Request for Additional Information
September 27, 1990	Response to Request for Additional Information
September 28, 1990	FDA Requested Additional Information
October 16, 1990	FDA Telephone Questionnaire for Additional Information
October 26, 1990	FDA Documented Telephone Questionnaire Dated 10/16/90
November 27, 1990	FDA Acknowledged Completion of IDE Final Report and Clinical Study

(jl)291188.jll

Ex. I

I hereby certify that this correspondence is being deposited with the United States Postal Service as first-class mail in an envelope addressed to:
Commissioner of Patents and Trademarks, Washington, D.C. 20231
on this 17th day of September, 1991.
By Laura B. Bertram

121*56

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

U.S. PATENT NO. 4,621,638

ISSUED: NOVEMBER 11, 1986

TO: THOMAS A. SILVESTRINI

FOR: HARD ELASTIC SUTURES

Hon. Commissioner of Patents and Trademarks
Washington, D.C. 20231

SUPPLEMENTAL DECLARATION OF GERALD H. SCHULZE

Gerald H. Schulze deposes and states that:

1) He is Senior Vice President of Pfizer Hospital Products Group, Inc. ("Applicant").

2) Human clinical studies on the subject non-absorbable polypropylene surgical suture (Deknatel Microflex Opthalmic Suture) began on March 1, 1988.

3) Attached to this Declaration as Exhibits "A" to "J" are true and correct copies of the following:

   A) Letter to Deknatel from the Food and Drug Administration ("FDA") dated January 12, 1988 assigning IDE No. G880005 to Deknatel IDE submission.

B) Letter to Deknatel from FDA dated February 5, 1988 conditionally approving Deknatel IDE.

C) Letter to Deknatel from FDA dated March 11, 1988 approving IDE supplement.

D) Letter to Deknatel from FDA dated February 6, 1989 approving IDE supplement.

E) Deknatel annual progress report dated February 28, 1989.

F) Deknatel annual progress report dated May 2, 1990.

G) Letter to Deknatel from FDA dated June 7, 1990 acknowledging completion of investigation.

H) Letter from Deknatel to FDA reflecting filing of 510(k) Premarket Notification.

I) Letter (incomplete) from FDA to United States Surgical Corporation, dated July 5, 1990, relating to reclassification of non-absorbable polypropylene surgical suture.

J) Federal Register, Vol. 56, No. 105, Friday May 31, 1991, pp. 24684-85, showing reclassification of the Deknatel device from Class III to Class II, effective July 5, 1990.

4) Applicant became aware of the reclassification some time very shortly after it became effective on July 5, 1990, when Deknatel received a copy of Exhibit 3(I).

5) That all statements made herein of his own knowledge are true, and that all statements made on information and belief are believed to be true, and further that these statements are

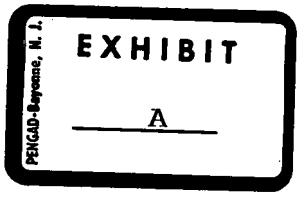
made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any extension of patent term granted thereon.

Sept. 16, 1991
Date

Gerald H. Schulze
Gerald H. Schulze

DEPARTMENT OF HEALTH AND HUMAN SERVICES — Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
8757 Georgia Avenue
Silver Spring, MD 20910



January 12, 1988

DEKNATEL
2300 MARCUS AVENUE
LAKE SUCCESS, NY 11042
ATTN: BETTY OROFINO

Dear Sponsor:

The information you have submitted, as required by the Food and Drug Administration (FDA) investigational device exemptions (IDE) regulation, has been assigned the following document control number:

IDE Number: G880005
Dated: 01/11/88
Received: 01/12/88
Device: ELASTIC POLYPROPYLENE SUTURE

FDA will notify you when the review of this submission has been completed or if any additional information is required. In accordance with Section 812.30 of the IDE regulation, you may begin your investigation 30 days after the date FDA received your submission, unless FDA notifies you that your investigation may not begin.

Any administrative questions concerning this submission should be directed to the IDE staff at (301) 427-8162. Any future correspondence regarding this submission should be identified with your IDE number and should be submitted, in triplicate, to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

Sincerely,

Timothy A. Ulatowski
Acting Director, IDE Staff
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

FEB 5 1988

Ms. Betty Orofino
Manager
Clinical and Regulatory Affairs
DEKNATEL
Division of Pfizer Hospital Products Group, Inc.
2300 Marcus Avenue
Lake Success, New York 11042

Re: IDE Number G880005
Elastic Polypropylene Suture
Dated: January 11, 1988
Received: January 12, 1988

Dear Ms. Orofino:

The Food and Drug Administration (FDA) has reviewed your investigational device exemptions (IDE) application. Your application is conditionally approved, and you may begin your investigation at New York Eye and Ear Infirmary, New York, New York and University Medical Center, Salt Lake City, Utah, after you have obtained institutional review board (IRB) approval and submitted certification of IRB approval to FDA. Your investigation is limited to 3 institutions and 30 subjects.

This approval is being granted on the condition that, within 30 days from the date of this letter, you submit information correcting the following deficiencies:

1. Include a space to record the tissue sutured on the patient report form.

2. Provide objective definitions for the rating scale used to evaluate tissue reaction.

3. Provide labeling for the device that includes the statement, "CAUTION - Investigational device. Limited by Federal (or United States) law to investigational use."

4. You must submit an environmental assessment as described by 21 CFR 25.31(a), or claim a categorical exclusion from this requirement by stating to us that "devices shipped under the Investigational Device Exemption are intended to be used for clinical studies in which waste will be controlled or the amount of waste expected to enter the environment may reasonably be expected to be nontoxic" as provided for in 21 CFR 25.24(e)(7).

This information should be identified as an IDE supplement referencing the IDE number above, and must be submitted in triplicate to:

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD 20910

If you do not provide this information within 30 days from the date of this letter, we may take steps to propose withdrawal of approval of your IDE application.

FDA will waive those requirements regarding the submission and prior FDA approval of a supplemental application and receipt of certification of IRB approval for the addition of investigational sites (21 CFR 812.35(b)) provided:

1. The total number of investigational sites does not exceed 3 and the total number of patients shall not exceed 30.

2. You maintain current records on:

   a. the names and addresses of all investigational sites,
   b. the names and addresses of all investigators, and identifying those that are currently participating,
   c. the names, addresses and chairpersons of all IRBs,
   d. the dates of the IRB approvals, and
   e. the dates of first shipments or first use of investigational devices for all participating institutions.

3. Within 5 days of reaching the investigational site limit, you submit to FDA a current list containing the information specified in 2(a-e) above.

4. The current investigator list to be submitted to FDA at 6-month intervals (21 CFR 812.150(b)(4)) will contain the information specified in 2(a-e) above.

5. You submit to FDA, within 2 days of receipt of a request by FDA, a current list containing the information specified in 2(a-e) above.

6. The reviewing IRB does not require any significant changes in the investigational plan or in the informed consent.

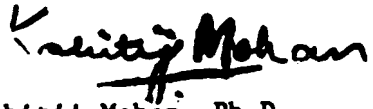
If you agree to these conditions, you may begin an investigation at a new investigational site after the IRB has approved the investigation. No documentation should be submitted for any institution within the approved limit until the investigational site limit is reached or the 6-month current investigator list is due. You must submit a supplemental IDE application, and receive FDA approval, prior to expanding the investigation beyond the limit specified above. If you do not agree to these conditions, you must comply with the full requirements of submission of a supplemental IDE application for new investigational sites (21 CFR 812.35(b)). FDA assumes that you have agreed to the conditions of this waiver unless you specifically notify us in writing of your disagreement.

We would like to point out that FDA approval of your IDE application does not imply that this investigation will develop sufficient data to assure a determination of substantial equivalence of a premarket notification (510(k)) submission or sufficient safety and effectiveness data to assure FDA approval of a premarket approval (PMA) application for this device. You may obtain the guideline for the preparation of a PMA application, entitled "Premarket Approval (PMA) Manual," from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or (301) 443-6597.

We have enclosed the guidance document entitled "Sponsor Responsibilities for a Significant Risk Device Investigation" to help you understand the functions and duties of a sponsor. Please contact the individuals listed below if you have any questions regarding these responsibilities.

If you have any questions, please contact Kenneth A. Palmer, Ph.D., at (301) 427-7238 or Mr. Timothy A. Ulatowski, at (301) 427-8162.

Sincerely yours,



Kshitij Mohan, Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

EXHIBIT
C
PENGAD-Bayonne, N. J.

MAR 11 1988

Ms. Betty Orofino
Clinical and Regulatory Affairs
DEKNATEL
Division of Pfizer Hospital Products Group, Inc.
2300 Marcus Avenue
Lake Success, New York 11042

Re: IDE Number G880005/S1
Elastic Polypropylene Suture
Dated: February 25, 1988
Received: February 26, 1988

Dear Ms. Orofino:

The Food and Drug Administration (FDA) has reviewed the supplement to your investigational device exemptions (IDE) application. You have corrected the deficiencies listed in our February 5, 1988 conditional approval letter. Therefore, your application is approved and you may conduct your investigation at the institutions listed in our February 5, 1988 letter where you have obtained institutional review board (IRB) approval. Your investigation is limited to 3 institutions and 30 subjects.

Sincerely yours,

Kshitij Mohan, Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

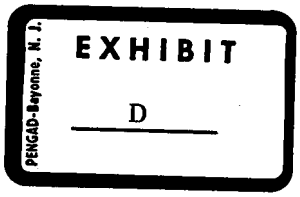
Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

FEB 6 1989

RECEIVED DEKNATEL

FEB 13 1989

REGULATORY AFFAIRS



Ms. Amy Peterson
Manager, Regulatory Affairs
Deknatel, Inc.
600 Airport Road
P.O. Box 2980
Fall River, Massachusetts 02722-2980

Re: IDE Number G880005/S3
Elastic Polypropylene Suture
Dated: January 9, 1989
Received: January 10, 1989

Dear Ms. Peterson:

The Food and Drug Administration (FDA) has reviewed the supplement to your investigational device exemptions (IDE) application proposing expansion of the number of investigational sites and patients enrolled in the study, and revision of the protocol to include the use of the continuous suturing technique. Your supplement is approved, and you may implement these changes at the institutions enrolled in your investigation. Your investigation is limited to 4 investigational sites and 120 patients (60 of which are to be control).

Since FDA believes this change affects the rights, safety or welfare of the subjects, you must also obtain institutional review board (IRB) approval before implementing this change in your investigation (21 CFR 812.35(a)).

We would like to point out that FDA approval of your supplement does not imply that this investigation will develop sufficient data to assure a determination of substantial equivalence of a premarket notification (510(k)) submission or sufficient safety and effectiveness data to assure FDA approval of a premarket approval (PMA) application for this device. You may obtain the guideline for the preparation of a PMA application, entitled "Premarket Approval (PMA) Manual," from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or (301) 443-6597.

You should also give serious consideration to the following items which are considered essential for the analysis of your data for the purpose of determining safety and effectiveness for a future PMA application:

You are reminded that any claims or indications for use statements that are made for this device must be substantiated with valid scientific evidence.

If you have any questions, please contact Mr. Kevin J. Crossen at (301) 427-7238 or Mr. Timothy A. Ulatowski at (301) 427-8162.

Sincerely yours,

Thomas J. Callahan for NKM

Nirmal K. Mishra, D.V.M., Ph.D.
Deputy Director, Division of
Surgical and Rehabilitation Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEKNATEL Inc.
a Pfizer company

600 AIRPORT ROAD, P. O. BOX 2980, FALL RIVER, MA 02722-2980 / PHONE 508-677-6600 / TELEX 493-8856 / FAX 508-677-6666

February 28, 1989

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
8757 Georgia Avenue
Silver Springs, MD 29010

Re: Annual Progress Report for Elastic Polypropylene Suture
IDE # G880005

This submission is being made in compliance with CFR 812.150 (b) (5) in fulfillment of the sponsors responsibility to provide a progress report at least yearly to FDA.

This report contains confidential information and we request its contents be provided the full protection as provided by the law.

If any questions exist, please contact the undersigned.

Sincerely,

Harry Savard

Harry Savard
Manager,
Regulatory Affairs
(508) 677-6487

AP/jl

TABLE OF CONTENTS

TABLE 1

CURRENT INVESTIGATOR LIST
ELASTIC POLYPROPYLENE SUTURE IDE G880005

Name/Address of Investigational Site	Name/Address of Investigators (Act.)	Name/Address of IRB Chairperson	Date IRB Appr'l.	Date of 1st Use
New York Eye & Ear Infirmary 310 East 14th Street New York, NY 10003	Clyde R. Lock, M.D. 38-04 28th Avenue Long Island City, NY	Michael W. Dunn,MD Co-Chariman IRB New York Eye & Ear Infirmary 310 East 14th St. New York, NY 10003	11/18/87 (Orig.) (update)	3/1/88
*University of Utah Health Services Center Department of Ophthalmology 50 North Medical Dr. Salt Lake City, UT 84132	Randall J. Olson, MD University Medical Center 50 North Medical Dr. Salt Lake City, UT 84132	Walter Stevens PhD IRB Chairman University of Utah Medical Center 50 North Medical Dr. Salt Lake City, UT 84132	11/18/87 (Orig.)	3/10/88
Veterans Admin. Medical Center 500 Foot Hill Blvd Salt Lake City, UT 84148	Randall J. Olson, MD Department of Ophthalmology University of Utah School of Medicine Salt Lake City, UT 84132	Andrew Deiss, MD Associate Chief of Staff for Research and Development 500 Foothill Blvd Salt Lake City, UT 84148	11/16/88	Not used to Date

Emory University School of Medicine Department of Ophthalmology 1327 Clifton Road, NE Atlanta, GA 30322	George O. Waring MD Department of Ophthalmology Emory University School of Medicine 1327 Clifton Road, NE Atlanta, GA 30322	Theodore Hersh, MD Chairman Human Investigators Committee Emory University School of Medicine Woodruff Health Services Center 1440 Clifton Road, NE Atlanta, GA 30322	4/22/88 (Orig.)	7/12/88

*Part of the IDE feasibility study only

DEKNATEL Inc
a Pfizer company

600 AIRPORT ROAD, P. O. BOX 2980, FALL RIVER, MA 02722-2980 / PHONE 508-677-6600 / TELEX 493-8856 / FAX 508-

May 2, 1990

Office of Device Evaluation
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

RE: ANNUAL PROGRESS REPORT: IDE #G880005/S7

Dear Sir/Madam,

Deknatel, Division of Pfizer Hospital Products Group, Inc., expects to submit a PMA supplement for our Deklene^{R} II Polypropylene Non-Absorbable Surgical Suture, U.S.P. for ophthalmic use on or about June 1, 1990.

We have completed the study approved under the subject IDE in support of this submission.

The PMA supplement will be filed in lieu of the required Annual Progress Report.

If you should have any questions, please contact me at (508) 677-6543.

Sincerely,

Harry Savard
Manager, Regulatory Affairs

HS\rc

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

JUN - 7 1990

Mr. Harry Savard
Manager, Regulatory Affairs
Deknatel, Inc.
600 Airport Road
P.O. Box 2980
Fall River, Massachusetts 02722-2980

Re: IDE Number G880005/S7
Deklene® II Polypropylene Non-absorbable
Surgical Suture, U.S.P. for Ophthalmic use
Dated: May 2, 1990
Received: May 8, 1990

Dear Mr. Savard:

The Food and Drug Administration (FDA) acknowledges the completion of your investigation. A final report must be submitted to FDA, all reviewing institutional review boards (IRBs) and all participating investigators within 6 months from completion of your investigation (21 CFR 812.150(b)(7)). We understand that you intend for your upcoming PMA submission to serve as the final report for this IDE application. You must submit an IDE supplement which references the PMA submission containing the final report. Your IDE application will not be considered closed until FDA receives the final report.

If you have any questions, please contact Ms. Diane Minear at (301) 427-1090 or Ms. Nancy F. Teague at (301) 427-1190.

Sincerely yours,

Carl A. Larson, Ph.D.
Director
Division of Surgical and
Rehabilitation Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEKNATEL
a Pfizer company

600 AIRPORT ROAD, P. O. BOX 2980, FALL RIVER, MA 02722-2980 / PHONE 508-677-6600 / TELEX 493-8856 / FAX 508-677-6666

August 21, 1990

Office of Device Evaluation
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

RE: FINAL REPORT
IDE# G880005

Dear Sir/Madam,

Please be informed that Deknatel Division, Pfizer Hospital Products Group, Inc., has filed a 510(k) Premarket Notification No. K903643, entitled "Deknatel MICROFLEX™ Ophthalmic Polypropylene Suture". Appendix H of the 510(k) document contains the Final Report for subject IDE# G880005 per 21 CFR 812.150(b)(7) Sponsor Reports-Final Report.

If you should have any questions, please contact me at (508) 677-6543.

Sincerely,

Harry Saward
Manager, Regulatory Affairs

HS/rc

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

JUL 5 1990

Mr. Walter S. Hennig
Vice President, Quality Functions
United States Surgical Corporation
150 Glover Avenue
Norwalk, Connecticut 06856

Re: **Reclassification of Nonabsorbable Polypropylene Surgical Suture, Docket Number 88P-0173**

Dear Mr. Hennig:

INTRODUCTION

The Center for Devices and Radiological Health (CDRH) for the Food and Drug Administration (FDA) has completed its review of your reclassification petition for the nonabsorbable polypropylene surgical suture. FDA concludes that the generic type of device, nonabsorbable polypropylene surgical suture, and all devices substantially equivalent to this generic type, should be reclassified from class III into class II with a low priority for the development of a performance standard. This order, therefore, reclassifies nonabsorbable polypropylene surgical sutures into class II effective immediately.

FDA identifies the generic type of device the subject of this reclassification, as follows:

> Nonabsorbable polypropylene surgical suture is a monofilament, nonabsorbable, sterile, flexible thread prepared from long-chain polyolefin polymer known as polypropylene and is indicated for use in soft tissue approximation. The polypropylene surgical suture meets USP requirements as described in the USP Monograph for Nonabsorbable Surgical Sutures; it may be undyed or dyed with an FDA approved color additive; and the suture may be provided with or without a standard needle attached.

As you know, on May 4, 1988, FDA filed the reclassification petition submitted by Advanced Biosearch Associates of Danville, California on your behalf requesting reclassification of nonabsorbable polypropylene surgical suture from class III into class II. The petition was submitted under section

88P-0173

classified under section 520(l)(1). Nothing in the act suggests that transitional device reclassification should be initiated under any section of the act other than section 520(l)(2).

The act's premarket notification requirement demonstrates further that this proceeding is authorized by the transitional device reclassification provisions. If any person were to file a premarket notification under section 510(k) of the act, 21 U.S.C. 360(k), he would be required to identify:

> The class in which the device is classified under section 513 or if such person determines that the device is not classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified (emphasis added). Id.

Clearly, nonabsorbable polypropylene surgical suture was not classified under section 513. Congress, as evidenced by the underlined portion of the above-quoted language, recognized that classification could occur outside of section 513. Section 520(l)(1) provides the only means of classifying a device outside of section 513 available under the act, and nonabsorbable polypropylene surgical suture was classified under the authority of that section. Accordingly, any person now bringing nonabsorbable polypropylene surgical suture to the market for the first time would be required to inform the agency in the context of section 510(k) of whether his nonabsorbable polypropylene surgical suture is substantially equivalent to a preamendment suture, as classified under section 520(l)(1), or a unique and, therefore, "new" suture as classified under section 513(f)(1).

For the nonabsorbable polypropylene surgical suture the subject of this reclassification proceeding, it is unchallenged that it was classified into class III under section 520(l)(1). Accordingly, since neither sections 520(l)(1) nor 520(l)(2) express any time restraints or other limitations regarding the acts of classification or reclassification of transitional devices, and since the Amendments, through premarket notification, intend that substantially equivalent devices, including transitional devices, be classified the same, I must conclude that the agency's position, that section 520(l)(2) describes the reclassification procedures for devices originally classified under section 520(l)(1), is reasonable and should be followed.[1]

---

[1] The agency's understanding of the transitional device provision is consistent with the act and the agency's regulations, and is also supported by legislative history, stating:

> [the] [o]pportunity to petition [under the transitional device provisions] for reclassification to class II or I is afforded the manufacturer or importer of any device classified into class III as a result of [section 520(l)(1).]

H.R. Rep. No. 853, 94th Cong., 2d Sess., February 29, 1976 at 38.

As the above discussion demonstrates, Congress intended to permit persons, who for the first time desire to manufacture or import transitional devices, the opportunity to seek reclassification under section 520(l)(2), notwithstanding the fact that reclassification was sought well after the passage of the Amendments. Moreover, U.S. Surgical, in our view and as the record shows, is an appropriate party to petition for reclassification under section 520(l)(2) in that the company intends to market nonabsorbable polypropylene surgical suture, and presently has received approval from FDA to export nonabsorbable polypropylene surgical suture to Italy, West Germany, France, The Netherlands and Switzerland (Ref. 150). Under these circumstances, U.S. Surgical, like any person submitting a premarket notification under section 510(k) seeking classification under section 520(l)(l), has standing to pursue reclassification under section 520(l)(2) from an automatic class III placement.

DECISION

After reviewing the publicly available literature in the record, the Panel's deliberation, and FDA's past actions regarding nonabsorbable polypropylene surgical suture, it is apparent to FDA that a class III designation for nonabsorbable polypropylene surgical suture constitutes overregulation.

By limiting the generic class, the subject of this order, to nonabsorbable polypropylene surgical suture, as defined on page 1, FDA, according to the record evidence, has limited this reclassification to nonabsorbable polypropylene surgical suture with the same or similar health risks. This approach is entirely consistent with FDA's definition of a generic type of device, see 21 CFR 860.3(i), and its view that "[t]he similarity of health risks is fundamental to the concept of classification by generic type of device," see 43 Fed. Reg. 32989, 32992 (July 28, 1978).

Additionally, U.S. Surgical has provided information in its petition to show that, despite variations in nonabsorbable polypropylene surgical suture materials and manufacturing processes, test methods exist to demonstrate whether any nonabsorbable polypropylene surgical suture is within the scope of the generic type of device identified in this order. Therefore, we believe that the nonabsorbable polypropylene surgical suture is well characterized and an appropriate candidate for reclassification.

As you have demonstrated, class II controls are appropriate to regulate nonabsorbable polypropylene surgical suture. Class II controls are indicated where class I controls alone are inadequate to reasonably assure a device's safety and effectiveness, and sufficient information exists to establish a performance standard to provide for such an assurance. See section 513(a)(l)(B) of the act, 21 U.S.C. 360c(a)(1)(B). As our discussion below demonstrates, the publicly available valid scientific evidence contained in the administrative record in this matter identifies the performance parameters and risks that define the safety and effectiveness of nonabsorbable polypropylene surgical suture. Also, valid scientific evidence in the record demonstrates the basis of a performance standard to control these parameters and risks and, thus, "sufficient information to establish a performance

standard," (see section 513(a)(1)(B)), exists to classify nonabsorbable polypropylene surgical suture into class II.

A class II classification may occur with or without an actual standard being in place. Of importance is the fact that enough is known about the performance of nonabsorbable polypropylene surgical suture that the generic premarket clearance criteria of a performance standard constitute a more appropriate level of regulatory control than the agency's product by product premarket review, mandated by class III controls. Indeed, the data in the record show that when weighing benefits to the probable risk of illness or injury resulting from the use of nonabsorbable polypropylene surgical suture, class III controls are unnecessary to assure the device's safe and effective performance.

In granting your petition, FDA has relied on valid scientific evidence, as defined by 21 CFR 860.7(c)(2). The agency's regulations prescribe various types of evidence that may be valid scientific evidence, including, for example, well-controlled studies and reports of significant human experience with marketed devices. Although a well-controlled investigation is a component of valid scientific evidence, it is important to appreciate that such an investigation is but one type of evidence that can be relied upon by FDA to make classification and other regulatory decisions.

FDA firmly believes that end-product test methods are available to thoroughly evaluate nonabsorbable polypropylene surgical suture, and that publicly available valid scientific evidence supports this conclusion. The agency contrues section 514 of the act to sanction the use of end-product testing as a means of evaluating the properties and performance of a device. In that nonabsorbable polypropylene surgical suture is considered by the agency to be well characterized, and the record evidence supports this conclusion, and since valid scientific evidence shows the applicability of various end-product tests to the use of the suture in humans, we believe that class II controls provide a reasonable means, consistent with the act's purpose, to regulate nonabsorbable polypropylene surgical suture.

SCIENTIFIC BASIS

Suture Characterization

By definition, the nonabsorbable polypropylene surgical suture is well characterized. The suture is a monofilament, nonabsorbable, sterile, flexible thread prepared from long-chain polyolefin polymer known as polypropylene and is indicated for use in soft tissue approximation. The polypropylene surgical suture meets USP requirements as described in the USP Monograph for Nonabsorbable Surgical Sutures; it may be undyed or dyed with an FDA approved color additive; and the suture may be provided with or without a standard needle attached.

The nonabsorbable polypropylene surgical suture manufacturing process begins with production of the isotatic form of the polypropylene polymer wherein the attached methyl groups are arranged in a stereoregular

configuration along one side of the "plane" described by a zig-zag carbon chain. It is produced in a solvent polymerization, using hydrocarbon solvent under pressure, at high temperatures and in the presence of a Zeigler-Natta catalyst which promotes the formation of the stereoregular isotatic form of the polypropylene polymer. The resulting insoluble isotatic polymer resin is subsequently purified by filtration and extraction to remove the catalyst, and then dried. Nonabsorbable polypropylene surgical suture may be left undyed (natural), or if desired, dyed with an FDA listed color additive in accordance with section 706 of the act.

The polypropylene resin is extruded at high temperature into polymer fibers of uniform diameter, and a specific multiple of their length are drawn or stretched to provide the necessary tensile properties. Nonabsorbable polypropylene surgical suture is ordinarily monofilamentous, and depending upon the final suture size desired, fibers of appropriate diameter and characteristics are produced. The processed thread is then cut to length, gauged to ensure uniform diameter and tensile strength in accordance with the requirements of United States Pharmacopeia (USP), appropriately packaged (with or without an attached needle), and sterilized to produce a finished suture (Refs. 7, 9, 29, 32, 65, 105, 133, 134 and 135).

Record data show that nonabsorbable polypropylene surgical suture's performance parameters and uses are well documented and understood, and that the generic type of device presents a reasonably uniform risk/benefit profile. Indeed the characteristics and composition of polypropylene are well-defined (Refs. 23, 24, 57, 58, 69, 72, 90, 91, 95, 113, 117, 120, 121, 126, 128-131, 134 and 135). Moreover, the performance parameters of existing nonabsorbable polypropylene surgical suture are well established (Refs. 9, 24, 29, 45, 50, 64, 121, 133, 134, 135 and 137) and the record shows the reasonably safe and effective use of nonabsorbable polypropylene surgical suture in humans (Refs. 17, 21, 33, 41, 42, 87, 95, 120 and 138).

The end product, given its indications for use, must have certain tensile strength characteristics (Refs. 9, 23, 28, 30, 34, 64, 74, 85, 89, 90, 91, 95, 113, 117, 120, 121, 126, 128, 129, 130, 133, 137 and 142). USP sutures, evaluated by uniform end-product testing, will perform successfully, notwithstanding different manufacturing processes (Refs. 7, 9, 64, 137, 24, 85, 133, 134 and 135), and will, among other things, have uniform tensile strengths. Since record data show that all nonabsorbable polypropylene surgical sutures present similar risks and performance characteristics (Refs. 9, 24, 29, 45, 50, 64, 121, 133, 134, 135 and 137), end product testing, in conjunction with other controls, will provide an appropriate means of reasonably assuring safe and effective nonabsorbable polypropylene surgical sutures.

In sum, the principal materials used to produce nonabsorbable polypropylene surgical suture is isotatic polypropylene polymer, and the physical characteristics of these polypropylene polymers are well understood. The USP Standard (Ref. 133 a-1), the American Society for Testing and Materials (ASTM) standards (Ref. 9 a-t) and other state-of-the-art test methods exist to evaluate and analyze the manufacturing process, composition, and physical, mechanical and biological properties of any nonabsorbable

of oxidative degradation vary according to exposure to ultraviolet radiation, and may make the use of the suture in the eye questionable (Refs. 4, 32, 42, 70 and 149). Oxidative enzyme activity and the type of tissue at the wound site, e.g., actively metabolizing tissues, tissues with high oxygen concentration, and inflammation may also contraindicate the suture for certain applications (Refs. 4, 32, 42, 43, 44, 70 and 149).

The patient's health and response to the suture material may affect wound healing (Refs. 11, 17, 18, 48, 66, 74, 80, 81, 87, 107, 108, 109 and 121). Patients whose health has been compromised or weakened by poor nutrition, advanced age, obesity, uncontrolled diabetes, infection, anemia, or with certain forms of cancer, may exhibit delayed wound healing (Refs. 11, 17, 18, 48, 66, 74, 80, 81, 87, 107, 108, 109 and 121) which may increase the likelihood of suture failure. Although some of these factors have been shown experimentally to delay increases in wound strength, a nonabsorbable suture, such as nonabsorbable polypropylene surgical suture, may be preferred over absorbable sutures due to the suture's continuous support of tissues (Refs. 17, 48, 66, 74, 108, 121 and 137).

The appropriate use of nonabsorbable polypropylene surgical suture is important in defining its performance. The record shows that nonabsorbable polypropylene surgical suture has been successfully used in various wound sites and conditions in humans (Refs. 17, 21, 33, 41, 42, 87, 95, 120 and 138). Although, wound dehiscence is most significant in wound closures involving sites which can undergo expansion, stretching, or distention, such as the abdomen, chest, and joints, nonabsorbable polypropylene surgical suture may be the suture of choice due to its continued support of tissues (Refs. 11, 17, 18, 22, 33, 48, 66, 74, 79, 80, 81, 87, 102, 108, 121 and 137). Using nonabsorbable polypropylene surgical suture to close certain wounds has documented advantages related to the physical properties of the suture (Refs. 11, 22, 33, 66, 74, 79, 80, 81, 87, 108 and 121).

Surgical technique also affects the performance of sutures, including nonabsorbable polypropylene surgical suture. Improper closure technique can result in tissue separation and failure of the wound to heal. The factors relating to the wound closure technique that contribute to wound dehiscence include the tightness with which sutures are tied, suture knot security, the adequacy of tissue bites to allow for adequate wound expansion due to distention and damage to the suture during placement (Refs. 11, 17, 18, 21, 23, 48, 57, 58, 64, 66, 69, 74, 77, 79, 83, 87, 95, 102, 107, 108, 109, 115, 117, 120, 121, 129 and 130).

The critical parameter of tensile strength can be controlled by standard in vitro test methods and animal testing. The tensile strength of nonabsorbable polypropylene surgical suture before implantation and after explantation may be measured in a motor-driven tensile strength machine using equipment and procedures described in the USP (Refs. 133, 134 and 135). Moreover, various American Society for Testing and Material (ASTM) tests to evaluate suture strength exist and include, for example, yarn breaking load, breaking tenacity in loop/knot configuration, single textile fiber tensile strength, and in vitro strength loss and material degradation tests (Refs. 9, 134 and 135). Finally, to determine the effects of implantation of

nonabsorbable polypropylene surgical suture upon tensile strength, various in vitro and in vivo methods used by Salthouse (Refs. 116 and 117), Postlethwait (Ref. 110), and others (Refs. 30, 64, 128, 129 and 130), which compare the tensile strength of various absorbable and nonabsorbable sutures, show a suture's performance characteristics.

The various evaluative methods included in the above references are applicable to the safe and effective use of nonabsorbable polypropylene surgical suture in humans in that sutures that have been successfully used in humans are routinely evaluated with these evaluative methods (Refs. 17, 21, 33, 41, 42, 87, 95, 120 and 138). Importantly, the time necessary for wound healing in various sites in humans is known (Refs. 2, 3, 5, 6, 13, 14, 19, 20, 24, 25, 27, 38, 39, 49, 50, 52, 60, 61, 63, 74, 75, 76, 77, 78, 98, 101, 103, 107, 114, 116, 121, 124, 127, 137 and 143), and the above methods permit a determination of whether sufficient suture tensile strength will be present over time to assure a successful result at any given wound site.

Also, many of the above-identified performance parameters and risks can be adequately controlled by labeling disclosures which may be incorporated into a class II standard or required by the class I misbranding controls, which include, among other things, the requirement of adequate directions for use. Disclosures can be made which contain warnings against the use of nonabsorbable polypropylene surgical suture in certain conditions, such as intracamerally in the eye. Also, risks may be avoided by disclosing in labeling that users must be familiar with surgical procedures and techniques involving nonabsorbable polypropylene surgical suture before using it to close wounds.

2. Tissue Inflammatory Response

A tissue inflammatory response is an acute or chronic, localized reaction. Many factors may cause a tissue inflammatory response, including trauma attributed to the implantation of a suture, (Refs. 17, 29, 50, 66, 89, 110, 116, 117, 121, 125, 126 and 137), and foreign body reactions to the suture material (Ref. 74, 87, 107, 119, 121, and 123).

Various studies have documented that an early tissue inflammatory reaction results from the trauma of inserting sutures and does not occur as a result of a reaction to suture material (Refs. 82, 84 and 144). When the suture is placed within tissue with little or no trauma, no inflammatory cell response results, suggesting the conclusion that the body's nonspecific response to tissue injury induces the appearance of inflammatory cells usually seen immediately after suturing (Refs. 31, 87, 107, 119, 146 and 147). The initial reaction of tissues after suturing reflects the amount of injury inherent in the process, and that injury typically is the same for all sutures 5 to 7 days after suturing (Refs. 17, 111, 121, 126, 127 and 137).

The inflammatory response observed beyond 5 to 7 days postoperatively is dependent upon the nature of the specific suture material employed. Specifically, synthetic materials elicit a lesser response than sutures of natural origin (Refs. 29, 110, 116, 117, 119, 121 and 136), and nonabsorbable polypropylene surgical sutures elicit a milder response than absorbable

sutures (Refs. 37, 89, 119, 126, 127 and 137). Additionally, fine gauge sutures provoke a lesser response than large diameter sutures because of their lesser mass and therefore lesser amount of implanted foreign material (Refs. 50 and 136).

Record data show that nonabsorbable polypropylene surgical suture elicits a very mild chronic inflammatory response (Refs. 29, 89, 110, 116, 117, 119, 121, 126, 127 and 137), and because it is ordinarily monofilamentous, this response is among the most benign elicited by any suture material (Ref. 110). Following the initial inflammatory phase, a mild chronic tissue response to nonabsorbable polypropylene surgical suture is seen which is typically characterized by gradual formation of a fibrous encapsulation of the suture with little or no persistent cellular response (Refs. 87, 107, 119, 146 and 147). The chronic tissue inflammatory response to nonabsorbable polypropylene surgical suture is observed to be mild, and less than that elicited by certain other sutures (Refs. 87, 107, 119, 146 and 147) even though the chronic inflammatory response to nonabsorbable polypropylene surgical suture may be associated with granuloma formation in certain circumstances and wound sites (Refs. 74, 87, 107, 119, 121 and 123).

Because of the biocompatability of the synthetic polypropylene material, nonabsorbable polypropylene surgical suture has not been associated with allergic and antigenic reactions. Although the manufacturing process may introduce impurities and residues that can cause tissue inflammatory response, numerous well-established biocompatibility tests provide methods to evaluate a suture's inflammatory potential, including USP tests for impurities and residues, or other state-of-the-art analytical methods (Refs. 8, 9, 10, 12, 51, 53, 62, 65, 72, 86, 93, 96, 97, 104, 106, 112, 132, 133, 134, 145 and 148).

In summary, the risk of early tissue inflammation resulting from trauma is related to the user technique and is no greater for nonabsorbable polypropylene surgical suture than for other suture material. Further, the foreign body response to nonabsorbable polypropylene surgical suture is mild in nature and, therefore, the suture in some circumstances may be preferred to other nonabsorbable sutures. Appropriate labeling disclosures related to tissue inflammation may indicate that all nonabsorbable sutures present an inflammatory response and that nonabsorbable polypropylene surgical suture is less pronounced than that of other nonabsorbable sutures. Moreover, to the extent the manufacturing process may cause residues that introduce a potential for allergic or antigenic reaction, which otherwise is not present with the nonabsorbable polypropylene surgical suture, well-established biocompatibility tests, as part of a standard, exist to evaluate the suture's inflammatory potential.

3. Infection

Although polypropylene surgical suture is manufactured and marketed as a sterile device in accordance with voluntary standards for sterility (Refs. 7, 9, 133 and 134), it, nonetheless, may exacerbate the effects of an existing wound infection, because of its composition, physical configuration, and duration of contact with tissue (Refs. 15, 16, 29, 31, 35, 36, 40, 45, 48, 50,

55, 56, 66, 73, 122, 123, 125, 127 and 141). It has been established that the presence of suture material in a wound increases the wound's susceptibility to infection where the suture serves as a conduit for the mechanical transport of bacteria (Refs. 15, 29, 31, 36, 40, 50, 55, 66, 73, 108, 123, 125, 127, 136 and 139). Also, materials which permit the adherence of the largest amount of bacteria cause the greatest degree of post-surgical infection (Refs. 31, 36, 56, 73 and 125). Indeed, a comparative study of 10 sutures demonstrates that the physical configuration and chemical nature of various suture materials, their coating mechanisms, and the duration of contact between the sutures and bacteria, contribute to the bacterial adherence of the suture (Ref. 31). The physical configuration of suture material is found to correlate positively with the degree to which sutures aggravate infected wounds (id.), and the use of suture coatings do not appear to reduce the suture-related infection rate (Refs. 36, 45, 50, 55, 123 and 127).

In the presence of infection or contamination, all sutures appear to potentiate the wound infection (Refs. 29, 45, 48, 50, 123 and 127). While nonabsorbable polypropylene surgical suture is not unique in its potential to exacerbate infection, it does appear to carry a somewhat lesser risk than other sutures in this regard (Refs. 16, 32, 40, 55, 95, 121, 123, 126, 138 and 170). The choice of suture material may, therefore, be critical when closing a wound in the presence of infection or potential infection. Because the nonabsorbable polypropylene surgical suture presents somewhat of a lesser risk than other sutures to potential infection, it is a suture of choice for infected wounds or contaminated wounds that present a substantial risk of infection (Refs. 16, 29, 32, 35, 40, 45, 48, 55, 73, 95, 123, 126, 138, 139, 140 and 141).

In summary, since suture selection may be a critical factor in avoiding the exacerbation of an infection, adequate labeling for the nonabsorbable polypropylene surgical suture, as part of a standard, could state that it is a suture of choice in closing infected or contaminated wounds.

4. Calculogenesis

Nonabsorbable polypropylene surgical suture, like other suture material, has been shown to be a nidus for calculogenesis when in contact with salt solutions of the bladder and biliary tract (Refs. 47, 66, 107 and 137). Calculi formation occurs on other natural and synthetic sutures in the bladder, and calculi formation appears to be dependant on the length of time the suture is in contact with urine in the bladder (Refs. 18, 47, 107, 117, and 137). Studies also report that nonabsorbable polypropylene surgical suture, and other sutures, when exposed to salt solutions in the common bile duct have been associated with stone formation (Refs. 18, 60 and 137).

The risk of calculogenesis resulting from implantation of nonabsorbable polypropylene surgical suture in either the urinary or biliary tract is related to the length of time the suture is in contact with a salt solution in those tracts. The risk of calculogenesis with nonabsorbable polypropylene surgical suture is typical of that associated with all nonabsorbable sutures. Thus, adequate labeling as part of a standard, can control this risk by stating that it is inadvisable to place nonabsorbable polypropylene surgical

suture, or for that matter, any suture, in contact with salt solutions in the body's urinary and biliary tracts.

Based on the information presented above, it can be concluded that nonabsorbable polypropylene surgical suture is well characterized and that there is sufficient publicly available valid scientific evidence to demonstrate that a performance standard can be established and used, in combination with the general controls, to provide reasonable assurance of the safety and effectiveness of nonabsorbable polypropylene surgical suture. For control of suture breakage, in particular, for control of suture tensile strength, a standard can assure device safety and effectiveness. See pages 8-9. Likewise, suture-related tissue inflammatory response can be controlled by a performance standard. See page 10.

The act's general controls also make a substantial contribution to the regulation of nonabsorbable polypropylene surgical suture. Manufacturing processes for nonabsorbable polypropylene surgical suture are and will be subject to FDA's Good Manufacturing Practice regulations, and the act's adulteration provisions. Moreover, labeling warnings and disclosures identified throughout this order will provide sufficient control of various nonabsorbable polypropylene surgical suture-related performance parameters or risks to reasonably assure the suture's safe and effective use.

PRIORITY FOR THE DEVELOPMENT OF A STANDARD

While valid scientific evidence demonstrates that a performance standard may be written to control the material, composition, and physical characteristic of this generic type of device in order to reasonably assure its safety and effectiveness, one is not immediately needed. Existing devices, within the generic type covered by this order, typically conform to voluntary standards, including USP standards for nonabsorbable surgical suture. Moreover, nonabsorbable polypropylene surgical suture, as currently manufactured, has established a reasonable record of safe and effective use. The basic properties, principles of manufacture, and appropriate indications and contra-indications for use of nonabsorbable polypropylene surgical suture are well-established, both scientifically and clinically, as documented in publicly available information contained in the petition (Refs. 28, 39, 63, 64, 75, 76, 90, 98, 107, 121, 125 and 134).

In this matter, significant publicly available information indicates that existing nonabsorbable polypropylene surgical sutures are generally safe and effective (Refs. 24, 29, 39, 63, 75, 76, 80, 85, 98, 107, 110, 117, 121 and 127). Thus, FDA concludes that development of a mandatory performance standard is not immediately necessary to protect the public health.

State-of-the-art test methods are well-established to evaluate and analyze the structure, composition, physical, chemical, mechanical, physicochemical and biological properties of any nonabsorbable polypropylene surgical suture to allow a precise determination to be made of the relative safety and effectiveness of marketed nonabsorbable polypropylene surgical sutures and those intended for commercial distribution. Thus, the determination of

comparable safety and effectiveness of future nonabsorbable polypropylene surgical suture and marketed sutures can be made in the context of a premarket notification under section 510(k) of the act, 21 USC 360(k).

FDA, therefore, respectfully disagrees with Panel's recommendation that the promulgation of a mandatory performance standard be a high priority. FDA concludes that development of a mandatory performance standard should be a low priority because the establishment of a regulatory standard is not immediately necessary to protect the public health.

CONCLUSION

Based on the information provided in the petition and presented at the panel meeting, and the information submitted to the administrative record, FDA concludes that the generic type of device, nonabsorbable polypropylene surgical suture, should be reclassified from class III to class II with a low priority for the development of a performance standard.

Sincerely yours,

Robert L. Sheridan
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Enclosure

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b.	=D	1423-82	Standard Method of Testing for Twist in Yarns by the Direct-Counting Method
c.	=D	1774-79	Standard Test Methods for Elastic Properties of Textile Fibers
d.	=D	2101-82	Standard Test Methods for Tensile Properties of Single Man-Made Textile Fibers Taken From Yarns and Tows
e.	=D	2256-80	Standard Test Method for Breaking Load (Strength) and Elongation of Yarn by the Single Strand Method
f.	=D	2257-80	Standard Test Method for Extractable Matter in Yarns
g.	=D	2259-85	Standard Test Methods for Shrinkage of Yarns in Boiling Water or Dry Heat
h.	=D	3217-79	Standard Test Methods for Breaking Tenacity of Man-Made Textile Fibers in Loop or Knot

			Configurations
i.	=D	3412-86	Standard Test Methods for Coefficient of Friction, Yarn to Yarn
j.	=D	3822-82	Standard Test Method for Tensile Properties of Single Textile Fibers
k.	=F	469-78	Standard Practice for Assessment of Compatibility of Nonporous Polymeric Materials for Surgical Implants With Regard to Effect of Materials on Tissue
l.	=F	719-81	Standard Practice for Testing Biomaterials in Rabbits for Primary Skin Irritation
m.	=F	720-81	Standard Practice for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test
n.	=F	748-82	Standard Practice for Selecting Generic Biological Test Methods for Materials an Devices
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c. Physical Tests, <851> Spectrophotometry and Light-Scattering
d. Physical Tests, <861> Sutures - Diameter
e. Physical Tests, <871> Sutures - Needle Attachment
f. Physical Tests, <881> Tensile Strength
g. Physical Tests, <661> Containers, Biological Tests -Plastics
h. Biological Tests, <85> Bacterial Endotoxins Test
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150. Letters from FDA to United States Surgical Corporation granting export rights of nonabsorbable polypropylene surgical suture to The Netherlands, Italy, France, Switzerland and West Germany.

List of Subjects in 10 CFR Part 110

Administrative practice and procedure, Classified information, Criminal penalty, Export, Import, Incorporation by reference, Intergovernmental relations, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements, Scientific equipment.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR part 110.

PART 110—EXPORT AND IMPORT OF NUCLEAR EQUIPMENT AND MATERIAL

1. The authority citation for part 110 continues to read as follows:

Authority: Secs. 51, 53, 54, 57, 63, 64, 65, 81, 82, 103, 104, 109, 111, 126, 127, 128, 129, 161, 181, 182, 183, 187, 189, 68 Stat. 929, 930, 931, 932, 933, 936, 937, 948, 953, 954, 955, 956, as amended, (42 U.S.C. 2071, 2073, 2074, 2077, 2092–2095, 2111, 2112, 2133, 2134, 2139, 2139a, 2141, 2154–2158, 2201, 2231–2233, 2237, 2239); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

Section 110.1(b)(2) also issued under Pub. L. 96–92, 93 Stat. 710 (22 U.S.C. 2403). Section 110.11 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152) and secs. 54c and 57d., 68 Stat. 473, 475 (U.S.C. 2074). Section 110.27 also issued under sec. 309(a), Pub. L. 99–440. Section 110.50(b)(3) also issued under sec. 123, 92 Stat. 142 (42 U.S.C. 2153). Section 110.51 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 110.52 also issued under sec. 186, 68 Stat. 955 (42 U.S.C. 2236). Sections 110.80–110.113 also issued under 5 U.S.C. 552, 554. Sections 110.30–110.35 also issued under 5 U.S.C. 553.

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 110.20–110.29, 110.50, and 110.120–110.129 also issued under secs. 161 b and i, 68 Stat. 948, 949, as amended (42 U.S.C. 2201 (b) and (i); and §§ 110.7a and 110.53 are also issued under sec. 161(o), 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

2. The definition of "utilization facility" in § 110.2 is revised to read as follows:

§ 110.2 Definitions.

• • • • •

Utilization facility means any nuclear reactor, other than one that is a production facility, and the following major components of a nuclear reactor:

(1) Pressure vessels designed to contain the core of a nuclear reactor;

(2) Primary coolant pumps;

(3) Fuel charging or discharging machines; and

(4) Control rods.

A utilization facility does not include the steam turbine generator portion of a nuclear power plant. For purposes of export from the United States under the jurisdiction of the Nuclear Regulatory Commission, a utilization facility does not include the Topaz II Reactor System, owned by the Union of Soviet Socialist Republics and imported into the United States pursuant to NRC License No. IR90002, issued January 4, 1991.

3. Section 110.5 is revised to read as follows:

§ 110.5 Licensing requirements.

Except as provided under subpart B of this part and the definition of utilization facility in § 110.2 of this part, no person may export any nuclear equipment or material listed in § 110.8 and § 110.9, or import any nuclear equipment or material listed in § 110.9a, unless authorized by a general or specific license issued under this part.

Dated at Rockville, MD, this 24th day of May, 1991.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 91–12906 Filed 5–30–91; 8:45 am]

BILLING CODE 7590–01–M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 101

[T.D. 91–47]

Changes in the Customs Service Field Organization; Apalachicola, Carrabelle, and Port St. Joe, FL

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Final rule, correction.

SUMMARY: In T.D. 91–47, published on May 16, 1991 (56 FR 22641), 19 CFR part 101 was amended to remove Apalachicola and Carrabelle, Florida from the list of ports of entry, and to change Port St. Joe, Florida from a port of entry to a Customs station. This document corrects errors which appeared in the Authority citation as well as a typographical error in that document.

EFFECTIVE DATE: July 15, 1991.

FOR FURTHER INFORMATION CONTACT: Joseph O'Corman, Office of Inspection and Control, 202–566–8425.

PART 101—GENERAL PROVISIONS [CORRECTED]

In FR Doc. 91–11634, on page 22642, in the first column the following corrections are made.

1. Authority: The Authority citation for part 101 should read "Authority: 5 U.S.C. 301, 19 U.S.C. 2, 66, 1202 (General Note 8, Harmonized Tariff Schedule of the United States), 1623, 1624."

§ 101.3 [Corrected]

2. The date of issuance of R.O. 7818 relating to Port St. Joe, Florida, should read "Feb. 17, 1938" instead of "Feb. 17, 1983."

Dated: May 24, 1991.

Kathryn C. Peterson,

Chief, Regulations and Disclosure Law Branch.

[FR Doc. 91–12823 Filed 5–30–91; 8:45 am]

BILLING CODE 4820–02–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket Nos. 88p–0179, 88p–0173, 88p–0136]

Food and Drug Administration

21 CFR PART 878

Medical Devices; Reclassification and Codification of Nonabsorbable Poly (Ethylene Terephthalate) Surgical Suture, Nonabsorbable Polypropylene Surgical Suture, and Nonabsorbable Polyamide Surgical Suture

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has issued orders in the form of letters to a manufacturer reclassifying the nonabsorbable poly(ethylene terephthalate) surgical suture, nonabsorbable polypropylene surgical suture, and nonabsorbable polyamide surgical suture, from class III to class II. The orders are being codified in the Code of Federal Regulations as specified herein.

DATES: The reclassifications were effective February 15, 1990, for the nonabsorbable polyamide surgical suture, and July 5, 1990, for the nonabsorbable poly(ethylene terephthalate) surgical suture and the nonabsorbable polypropylene surgical suture. These codifications become effective (July 1, 1991).

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–4874.

SUPPLEMENTARY INFORMATION: On May 4 and 10, 1988, and April 7, 1988, FDA

filed the reclassification petitions submitted by Advanced Biosearch Associates, Danville, CA 94528-4817, on behalf of United States Surgical Corp. (U.S. Surgical), Norwalk, CT 06856, requesting reclassification of the nonabsorbable poly(ethylene terephthalate) surgical suture, nonabsorbable polyamide surgical suture, and the nonabsorbable polypropylene surgical suture from class III to class II.

FDA consulted with the General and Plastic Surgery Devices Panel (the Panel). The Panel, during an open public meeting on October 20, 1988, recommended that FDA reclassify nonabsorbable polypropylene surgical suture and the nonabsorbable poly(ethylene terephthalate) surgical suture from class III into class II.

On June 24, 1988, the Panel recommended that FDA reclassify the nonabsorbable polypropylene surgical suture from class III into class II. FDA fully considered the Panel's recommendation, and reviewed various statements offered by persons who opposed U.S. Surgical's petitions for reclassification of the nonabsorbable polypropylene surgical suture, the nonabsorbable poly(ethylene terephthalate) surgical suture, and the nonabsorbable polypropylene surgical suture. FDA concluded that these generic types of devices, and all devices substantially equivalent to them should be reclassified from class III to class II.

After reviewing all data in the petition and presented before the Panel, and after considering the Panel's recommendation, FDA, based on the information set forth, ordered the reclassification of the nonabsorbable polypropylene surgical suture, the nonabsorbable poly(ethylene terephthalate) surgical suture, and the nonabsorbable polypropylene surgical suture from class III to class II. On July 5, 1990, FDA sent to the petitioner letters (orders) which reclassified the nonabsorbable polypropylene surgical suture and the poly(ethylene terephthalate) surgical suture, and substantially equivalent devices of these generic types, from class III to class II. On February 15, 1990, FDA sent the petitioner a letter (order) which reclassified the nonabsorbable polyamide surgical suture, and substantially equivalent devices within the reclassified generic type, from class III to class II. As required by 21 CFR 860.134 (b)(6) and (b)(7) of the regulations, FDA is announcing the reclassification of these generic types. In addition, FDA is codifying the reclassification of these devices by adding §§ 878.5000, 878.5010, and 878.5020 to subpart E.

The agency has determined under 21 CFR 25.24 (a)(8) and (e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

After considering the economic consequences of approving this reclassification, FDA certifies that this final rule requires neither a regulatory impact analysis as specified in Executive Order 12291 nor an analysis under the Regulatory Flexibility Act (Pub. L. 96-354). This reclassification will not have a significant economic impact on a substantial number of small entities. All manufacturers of nonabsorbable poly(ethylene terephthalate) surgical suture, nonabsorbable polypropylene surgical suture, and nonabsorbable polyamide surgical suture will no longer be required to comply with the premarket approval requirement in section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) and, therefore, will not be subject to the costs of such compliance.

There are no offsetting costs that manufacturers would incur from reclassification into class II other than those associated with meeting a standard, once established. The magnitude of the economic savings attributable to this reclassification is dependent upon the number of premarket approval studies that would have been required of the manufacturers had reclassification not occurred. This savings may not be reliably calculated to permit an accurate quantification of the economic savings.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under this Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. New §§ 878.5000, 878.5010, and 878.5020 are added to subpart E to read as follows:

§ 878.5000 Nonabsorbable poly(ethylene terephthalate) surgical suture.

(a) *Identification.* Nonabsorbable poly(ethylene terephthalate) surgical suture is a multifilament, nonabsorbable, sterile, flexible thread prepared from fibers of high molecular weight, long-chain, linear polyesters having recurrent aromatic rings as an integral component and is indicated for use in soft tissue approximation. The poly(ethylene terephthalate) surgical suture meets U.S.P. requirements as described in the U.S.P. Monograph for Nonabsorbable Surgical Sutures; it may be provided uncoated or coated; and it may be undyed or dyed with an appropriate FDA listed color additive. Also, the suture may be provided with or without a standard needle attached.

(b) Classification. Class II.

§ 878.5010 Nonabsorbable polypropylene surgical suture.

(a) *Identification.* Nonabsorbable polypropylene surgical suture is a monofilament, nonabsorbable, sterile, flexible thread prepared from long-chain polyolefin polymer known as polypropylene and is indicated for use in soft tissue approximation. The polypropylene surgical suture meets United States Pharmacopeia (U.S.P.) requirements as described in the U.S.P. Monograph for Nonabsorbable Surgical Sutures; it may be undyed or dyed with an FDA approved color additive; and the suture may be provided with or without a standard needle attached.

(b) *Classification.* Class II.

§ 878.5020 Nonabsorbable polyamide surgical suture.

(a) *Identification.* Nonabsorbable polyamide surgical suture is a nonabsorbable, sterile, flexible thread prepared from long-chain aliphatic polymers Nylon 6 and Nylon 6,6 and is indicated for use in soft tissue approximation. The polyamide surgical suture meets United States Pharmacopeia (U.S.P.) requirements as described in the U.S.P. monograph for nonabsorbable surgical sutures; it may be monofilament or multifilament in form; it may be provided uncoated or coated; and it may be undyed or dyed with an appropriate FDA listed color additive. Also, the suture may be provided with or without a standard needle attached.

(b) *Classification.* Class II.

Dated: May 20, 1991.

Ronald G. Chesemore,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 91-12954 Filed 5-30-91; 8:45 am]

BILLING CODE 4160-01-M

EX. IV

DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT

P.L. 98-417, see page 98 Stat. 1585

Senate Report (Judiciary Committee) No. 98-547, June 26, 1984 [To accompany S. 1538]

House Report (Energy and Commerce Committee) No. 98-857(I), June 21, 1984 [To accompany H.R. 3605]

House Report (Judiciary Committee) No. 98-857(II), Aug. 1, 1984 [To accompany H.R. 3605]

Cong. Record Vol. 130 (1984)

DATES OF CONSIDERATION AND PASSAGE

Senate June 29, August 10, September 12, 1984

House September 6, 1984

S. 1538 was passed in lieu of the House bill after amending its language to contain the text of the House bill. The House Report (Part I, this page, and Part II, page 2686) and a Related Report (page 2721) are set out.

HOUSE REPORT NO. 98-857, Part I

[page 1]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 3605) to amend the Federal Food, Drug, and Cosmetic Act to authorize an abbreviated new drug application under section 505 of that Act for generic new drugs equivalent to approved new drugs, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

* * * * *

[page 14]

PURPOSE AND SUMMARY

TITLE I

The purpose of Title I of the bill is to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962. Under current law, there is a generic drug approval procedure for pioneer drugs approved before 1962, but not for pioneer drugs approved after 1962.

Title I of the bill generally extends the procedures used to approve generic copies of pre-62 drugs to post-62 drugs. Generic copies

of any drugs may be approved if the generic is the same as the original drug or so similar that FDA has determined the differences do not require safety and effectiveness testing.

Title I also requires patent owners to submit information to FDA regarding produce and use patents that cover approved drugs. Generic copies of these drugs may be approved when the patents expire unless the generic company certifies that the patent is invalid or will not be infringed. In such cases, the generic company must notify the patent owner about its certification and approval of the generic drug may not be made effective until the court decides the suit for patent infringement or a period of 18 months, whichever occurs first. Notification must be given when the generic has submitted an ANDA with bioequivalence data.

In addition, Title I affords four years of exclusive market life to drugs which may not be patented and which are approved for the first time after enactment of the bill. Further, drugs which were approved for the first time between 1982 and the date of enactment received ten years of exclusive market life.

TITLE II

The purpose of Title II of the bill is to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval. The incentive is the restoration of some of the time lost on patent life while the product is awaiting pre-market approval. Under currrent law, a patent continues to run while the maker of the product is testing and awaiting approval to market it.

Title II of H.R. 3605 provides for one extension of the earliest patent on certain products subject to pre-market approval. The extension would be for a period equal to: (1) half of the time required to test the product for safety (and effectiveness in some cases); and (2) all of the time required for the agency to approve marketing of the product. These products include: human drugs, animal drugs, medical devices, and food and color additives.

Title II places several limits on the period of patent extension. First, the period of extension may not exceed two years for products either currently being tested or awaiting approval. For all other products, the period of extension may not exceed five years, Second, the period of patent extension when added to the patent time left after approval of the product may not exceed fourteen years. Third, any time that the product's manufacturer did not act with due diligence during the regulatory review period would be subtracted.

Finally, Title II provides that it is not an act of patent infringement for a generic drug maker to import or to test a patented drug in preparation for seeking FDA approval if marketing of the drug would occur after expiration of the patent.

HEARINGS

The Committee's Subcommittee on Health and the Environment held one day of hearings on H.R. 3605, the Drug Price Competition Act, on July 15, 1983. Testimony was received from 15 witnesses,

representing nine organizations, with additional material submitted by two individuals and organizations.

COMMITTEE CONSIDERATION

On August 2, 1983, the Committee's Subcommittee on Health and the Environment met in open session and ordered favorably reported H.R. 3605 without amendment by voice vote. On June 12, 1984, the Committee met in open session on H.R. 3605, amended the bill, and ordered it favorably reported by a voice vote. The title of the bill, as amended, is the "Drug Price Competition and Patent Term Restoration Act of 1984."

BACKGROUND AND NEED FOR THE LEGISLATION

TITLE I—ABBREVIATED NEW DRUG APPLICATIONS

Prior to 1962, the Federal Food, Drug and Cosmetic Act (FFDCA) required that all drugs be approved as safe before they could be marketed. The 1962 amendments required that all new drugs, generic and pioneer, must be approved as safe and effective prior to marketing.

As a result of the 1962 amendments, FDA did two things regarding pre-1962 drugs. First, the agency created the Drug Efficacy Study (DESI) to determine if all pre-1962 drugs were effective. Second, FDA established a policy permitting the approval of a generic drug equivalent to a safe and effective pre-1962 pioneer drug.

As a result of the 1962 amendments, the manufacturer of a pioneer drug must conduct tests on humans that show the product to be safe and effective and submit the results in a new drug application (NDA). A manufacturer of a generic drug must conduct tests that show the generic drug is the same as the pioneer drug and that it will be properly manufactured and labeled. This information is submitted in an abbreviated new drug application (ANDA).

The only difference between a NDA and an ANDA is that the generic manufacturer is not required to conduct human clinical trials. FDA considers such retesting to be unnecessary and wasteful because the drug has already been determined to be safe and effective. Moreover, such retesting is unethical because it requires that some sick patients take placebos and be denied treatment known to be effective.

The FDA allows this ANDA procedure only for pioneer drugs approved before 1962. There is no ANDA procedure for approving generic equivalents of pioneer drugs approved after 1962. While the FDA has been considering since 1978 an extension of the pre-1962 ANDA policy to post-1962 drugs, it has not extended the regulation. Because of the agency's failure to act, Title I of H.R. 3605 is necessary to establish a post-1962 ANDA policy.

Some have suggested that "Paper NDAs" be used to approve generic equivalents of pioneer drugs approved after 1962. Under the Paper NDA procedure, the generic manufacturer may submit scientific reports, instead of clinical trials, to support findings of safety and efficacy. This procedure is inadequate, however, because FDA estimates that satisfactory reports are not available for 85 percent of all post-1962 drugs.

Currently, there are approximately 150 drugs approved after 1962 that are off patent and for which there is no generic equivalent. All of these drugs could be approved in generic form if there was a procedure. Each year, more pioneer drugs go off patent and become available for approval as generics.

Among the drugs available or soon to be available for generic approval are five best sellers: valium, motrin, inderal, dyazide, and lasix. Dyazide, for example, is the most widely used diuretic for the treatment of high blood pressure. Its patent expired in 1981. Valium is a popular tranquilizer whose patent expires in 1985. Another drug whose patent has expired is indocin, an anti-inflammatory drug used in the treatment of arthritis that is the tenth highest selling drug in the United States.

The availability of generic versions of pioneer drugs approved after 1962 would save American consumers $920 million over the next 12 years. Older Americans, in particular, would benefit because they use almost 25 percent of all prescription drugs.

Moreover, the lack of generics for post-1962 pioneer drugs will cost Federal and State governments millions of dollars. For the drug metronidazole, purchased by the Department of Defense, the taxpayers saved approximately $1.2 million in one year as a result of the availability of a lower priced generic version. Federal and State governments will be denied comparable savings on drugs approved after 1962 because of the lack of an approval procedure.

TITLE II—PATENT TERM RESTORATION

Patents are designed to promote innovation by providing the right to exclude others from making, using, or selling an invention. They enable innovators to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities.

Although the patent term in the United States is 17 years, the period during the patent term in which products are marketed (the effective patent term) is usually less than 17 years because patents often are obtained before products are ready to be marketed.

Effective patent terms are influenced by many factors, including Federal premarketing and premanufacturing regulations. The products covered by these regulations include pharmaceuticals, medical devices, food additives, and color additives. Pharmaceuticals for instance cannot be marketed in the United States until they have been approved by the Food and Drug Administration (FDA). To obtain such approval, drugs must undergo extensive testing to prove they are both safe and effective. All these products are subject to different regulations that have had varying impacts on effective patent terms.

In testimony before several Congressional committees, representatives from the pharmaceutical firms that are heavily involved in basic research and rely upon patents, claimed that the average effective patent term of drugs has declined. They argued that a continuation of the decline would result in decreased expenditures for research and development and, eventually, in a decline in the introduction of new drugs.

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As compensation for the loss of patent term due to government review, the research intensive firms argued for patent term extension legislation. They stated that the legislation would create a significant, new incentive which would result in increased expenditures for research and development, and ultimately in more innovative drugs.

Committee Oversight Findings

Pursuant to clause 2(l)(3)(A) of Rule XI of the Rules of the House of Representatives, the Committee reports that oversight of the Food and Drug Administration and the Federal Food, Drug, and Cosmetic Act was conducted by the Subcommittee on Health and the Environment. A hearing was held on July 15, 1983. The findings of the Committee's oversight activities have been incorporated into the legislation and are discussed in those portions of this report entitled "Background and Need for the Legislation" and "Section-by-Section Analysis."

Committee on Government Operations

Pursuant to clause 2(l)(3)(D) of rule XI of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Operations.

Committee Cost Estimate

In compliance with clause 7(a) of rule XIII of the Rules of the House of Representatives, the Committee believes that the costs, if any, incurred in carrying out H.R. 3605 will be offset by savings to the Federal government. In testifying before the Committee's Subcommittee on Health and the Environment, officials from the Food and Drug Administration estimated that any greater workload resulting from the approval of generic drugs under Title I would be absorbed initially. Later, the officials estimated, some additional staff might be required to process generic drug applications. This additional staff could cost up to $1.1 million. The actual cost to the Federal government cannot be estimated because it is unknown how much additional staff, if any, might be hired.

Enactment of the legislation, however, will result in significant cost savings to the Federal government. Unlike the costs of H.R. 3605, these savings are certain. The Federal government spent about $2.4 billion for drugs in 1983. Many of these drugs will be available as low cost generic after enactment of H.R. 3605. For example, the Department of Defense saved approximately $1.2 million in one year when a lower priced generic version of metronidazole became available.

Congressional Budget Office Estimate

Pursuant to clauses 2(l)(3) (B) and (C) of rule XI of the Rules of the House of Representatives, the Committee sets forth the following letter and cost estimate prepared by the Congressional Budget Office with respect to the reported bill:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, June 19, 1984.

Hon. JOHN D. DINGELL,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has reviewed H.R. 3605, the Drug Price Competition and Patent Term Restoration Act of 1984, as ordered reported by the House Committee on Energy and Commerce on June 12, 1984.

Title I of this bill would allow drug manufacturers to use an abbreviated new drug application (ANDA) when seeking approval to make generic copies of drugs that were approved by the Food and Drug Administration (FDA) after 1962. An estimated 150 drug products approved after 1962 are currently off patent and would become available for generic copy using the ANDA procedure proposed in this bill.

The FDA estimates that the enactment of H.R. 3605 would at least triple the workload of the division responsible for approving ANDAs. Currently, this division reviews ANDAs for generic copies of pre-1962 approved drug products. The workload would increase as several manufacturers file an ANDA for each drug product that becomes available for generic copy. Because they would be reviewing information on new drugs, the FDA believes it would take them a year to process each of the new applications. This is about three months longer on average than it currently takes to process a pre-1962 ANDA. Dr. Marvin Seife, Director of FDA's Division of Generic Drug Monographs, testified before the Subcommittee on Health and the Environment that a greater workload could at first be absorbed, but may later require additional office space and 15 new FDA employees. Assuming an average full-time equivalent position plus overhead and fringe benefits is $70,000, the potential cost to the FDA of implementing this legislation could be about $1.1 million. The actual cost to the federal government would depend on the extent to which the FDA would expand to accomodate the increased workload.

Enactment of this legislation could also result in savings to both the federal and state and local governments. In fiscal year 1983, the federal government spent approximately $2.4 billion for drugs in the Medicaid program, and in veteran and military hospitals. Data on drug costs in the Medicare program are unavilable. If the federal government is currently purchasing these 150 copiable drug products at higher, brand name prices, savings may result if lower priced, generic copies of these drugs are substituted.

It is difficult to know in advance which of the available 150 drug products manufacturers would choose to copy. It is also difficult to estimate the price at which these generic copies would be sold. Generic versions of ten popular drug products show their price to be on average 50 percent less than their brand name equivalent. The dollar amount the federal government currently spents on these 150 brand name drug products is unknown.

Title II of this bill would extend the amount of time for which certain patents are issued to include some or all of the time re-

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quired for a manufacturer to test a product for safety and efficacy and to receive marketing approval. Products affected by this legislation would be drugs, medical devices, and food and color additives. Manufacturers must show due diligence in their product testing or this amount of time will be subtracted from the total life of the patent. This provision would place an additional burden on the FDA. They would be responsible for keeping track of a manufacturer's product testing time and for determining their diligence in completing the testing. These costs, however, would be negligible.

Enactment of this bill could result in increased personnel costs to the federal government of approximately $1.1 million. The bill, however, does not specifically authorize additional appropriations for the FDA. This bill may also result in savings if cheaper, generic drugs are made available for purchase by the federal government. These savings would occur in various programs throughout the budget such as Medicare, Medicaid, and the Veterans Administration. However, the magnitude of these savings is unknown.

Please call me if I can be of additional assistance, or your staff may wish to contact Carmela Pena (226-2820) of our Budget Analysis Division for further details on this estimate.

Sincerely,

ERIC HANUSHEK
(For Rudolph G. Penner, Director).

INFLATIONARY IMPACT STATEMENT

Pursuant to clause 2(l)(4) of rule XI of the Rules of the House of Representatives, the Committee makes the following statement with regard to the inflationary impact of the reported bill:

The Committee believes that enactment of H.R. 3605 will not have an inflationary impact upon the economy. In fact, Title I of the bill will have a deflationary effect because it makes available lower priced generic versions of drugs. Such generic drugs are three to fifteen times less costly than their brand name counterparts. The estimated $1 billion cost savings to consumers as a result of Title I's generic drug approval procedure will have a deflationary effect upon the national economy. While Title II of the bill provides for a limited extension of the patents on certain products, the Committee believes that the additional patent term will act as a spur to develop innovative and, ultimately, less costly treatments for diseases.

SECTION-BY-SECTION ANALYSIS

TITLE I—DRUG PRICE COMPETITION ACT

Section 101

Section 101 amends section 505 of the Federal Food, Drug and Cosmetic Act (FFDCA)[1] to establish a new subsection (J) providing for the approval of abbreviated new drug applications (ANDA). Paragraph (1) of subsection (j) sets forth the information which must be included in an ANDA.

[1] 21 U.S.C. 355.

ANDA's for drugs which are the same

In the case of drugs which are the same as the listed drug, the focus of the bill is to provide the Food and Drug Administration (FDA) with sufficient information to assure that the generic drug is the same as the listed drug [2] that has previously been determined to be safe and effective. Some have suggested that a generic drug must be identical in all respects to the listed drug instead of the same. The regulations that permit ANDA's for pre-1962 pioneer drugs make no such distinction.[3] In rejecting the use of the term identical, the FDA regulation comments that "identical means a product that is the same in dosage form, strength, and route of administration, contains the same active ingredient, and is recommended for use under the same conditions of use."[4] The Committee has adopted the FDA's policy of utilizing the term "same" except that the bill permits an ANDA to be approved for less than all of the indications for which the listed drug has been approved as explained below.

First, an ANDA must include sufficient information to show that the conditions of use for which the applicant is seeking approval are the same as those that have been previously approved for the listed drug. The applicant need not seek approval for all of the indications for which the listed drug has been approved. For example, if the listed drug has been approved for hypertension and angina pectoris, and if the indication for hypertension is protected by patent, then the applicant could seek approval for only the angina pectoris indication.

While the FDA's current regulations for considering ANDA's for pioneer drugs approved before 1962 permit an applicant to petition for approval for an indication other than that which has been approved for the pioneer drug, section 101 of the bill overturns that policy.[5] Thus, an ANDA may not be considered for a condition of use that has not been previously approved for the listed drug.

An ANDA must also contain sufficient information to show that the active ingredients of the generic drug are the same as those of the listed drug. If the listed drug has one active ingredient, then the active ingredient of the generic must be the same. If the listed drug has more than one active ingredient, then sufficient information must be included to show that all of the active ingredients in the generic drug are the same.

In addition, an ANDA must contain sufficient information to show that the route of administration, the dosage form and the strength of the generic drug are the same as those of the listed drug.

Further, an ANDA must include sufficient information to show that the generic drug is bioequivalent to the listed drug.

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[2] The term "listed drug" is explained in paragraph (6) of new section 505(j) of the FFDCA. Generally, a listed drug includes any drug that has been approved for safety and effectiveness or that has been approved under new subsection (j).

[3] 48 Fed. Reg. 2751 (1983).

[4] Id. at 2753.

[5] Id. at 2755.

21 C.F.R. 314.2(c) provides in part:

"A prospective applicant may seek a determination of the suitability of an abbreviated new drug application for a product that the applicant believes similar or related to a drug product that has been declared to be suitable for an abbreviated new drug application . . ."

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Fifth, an ANDA must contain adequate information to show that the proposed labeling for the generic drug is the same as that of the listed drug. The Committee recognizes that the proposed labeling for the generic drug may not be exactly the same. For example, the name and address of the manufacturers would vary as might the expiration dates for the two products. Another example is that one color is used in the coating of the listed drug and another color is used in that of the generic drug. The FDA might require the listed drug maker to specify the color in its label. The generic manufacturer, which has used a different color, would have to specify a different color in its label.

Sixth, an ANDA must include a list of all the components of the generic drug, a description of the composition of the generic drug, a description of the methods and controls used in the manufacture, processing and packing of the generic drug, samples of the generic drug and its components, and specimens of the proposed labeling.

Seventh, an ANDA must include a certification by the applicant regarding the status of certain patents applicable to the listed drug if the patent information has been submitted under section 505 (b) or (c). With respect to all product patents which claim the listed drug and all use patents which claim an indication for the drug for which the applicant is seeking approval (hereafter described as a controlling use patent), the applicant must certify, in his opinion and to the best of his knowledge, as to one of four circumstances.

The applicant may certify that the patent information required under sections 505 (b) and (c) has not been submitted if that is the case. If appropriate, the applicant may certify that one or more of the product or controlling use patents provided have expired. Third, the applicant may certify when appropriate that one or more of the product or controlling use patents will expire at some specified date in the future. When the applicant makes these certifications, it must rely upon the patent information supplied to the FDA. Last, an applicant may certify if applicable that one or more of the product or controlling use patents are invalid or will not be infringed.

The Committee recognizes that in some instances an applicant will have to make multiple certifications with respect to product or controlling use patents. For example, if the product patent has expired and a valid controlling use patent will not expire for three years, then the applicant must certify that one patent has expired and the other will expire in three years. The Committee intends that the applicant make the appropriate certification for each product and controlling use patent.

Eighth, if there are indications which are claimed by any use patent and for which the applicant is not seeking approval, then an ANDA must state that the applicant is not seeking approval for those indications which are claimed by such use patent. For example, the listed drug may be approved for two indications. If the applicant is seeking approval only for indication No. 1, and not indication No. 2 because it is protected by a use patent, then the applicant must make the appropriate certification and a statement explaining that it is not seeking approval for indication No. 2.

Finally, the Committee intends that an ANDA contain any information available to the applicant regarding reports of adverse ef-

fects not reflected in the labeling, an environmental impact analysis pursuant to FDA regulations, statements regarding the protection of human subjects in clinical investigations as required by FDA regulations, and a statement regarding compliance with good laboratory practices in non-clinical investigations as required by FDA regulations.[6]

ANDA's for drugs which are different

Paragraph (2)(C) prohibits any person from submitting an ANDA for a generic drug which differs from the listed drug unless the change is permitted by the statute and the FDA has granted a petition requesting the change.

If an applicant wishes to vary the route of administration, dosage form or strength of the generic drug from the listed drug, it must first petition the FDA for permission to file an ANDA for the differing generic drug. In addition, an applicant may request to vary one of the active ingredients in the generic drug from the listed drug when the listed drug is a combination product. The remaining active ingredients of the generic drug must be the same as the other active ingredients of the listed drug.

These are the only changes from the listed drug for which an applicant may petition. As is explained in the ANDA regulations for pre-1962 drugs, the Committee generally expects that approval of petitions will "ordinarily be limited to dosage forms for the same route of administration or to closely related ingredients."[7] If the FDA grants a petition for a change from the listed drug, the FDA may require such additional information in the ANDA regarding the change as it deems necessary.

The FDA must approve a petition to submit an ANDA for a differing generic drug unless clinical studies are needed to show the safety and effectiveness of the change. In reviewing a petition to change one of the active ingredients in a combination product, the Committee does not intend to change the FDA's current policy regarding the evaluation of the safety and effectiveness of combination products. If the FDA finds that safety and effectiveness testing of the active ingredients of the drug, individually or in combination, is required, then the FDA must deny the petition.

The FDA must either approve or disapprove a petition within 90 days of its submission. As is the case under the current regulations, "there is no legal requirement that the hearing opportunity provided by section 505(c) be made available to ANDA applicants who disagree with an adverse agency decision" on whether clinical studies are needed to show the safety and effectiveness of the differing generic drug.[8] "Appropriate review of such decisions may be had . . . under the applicable standard—that applicable to administrative decisionmaking generally—which is whether the agency's decision is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law (5 U.S.C. 706(2)(A)))."[9] If the FDA

[6] Id. at 2756. See 21 CFR 314.2(f) (4), (5), (6), (7), and (8).
[7] Id. at 2755. See 21 CFR 314.2(c).
[8] Id. at 2752.
[9] Id.

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(5), (6), (7), and (8).

does not approve a petition, then an ANDA may not be filed for a generic drug that varies from the listed drug.

An ANDA for a drug which differs from the listed drug and for which a petition has been approved by the FDA must contain such additional information regarding the difference as the FDA may require when it granted the petition. For example, if the route of administration of the generic drug differs from that of the listed drug, then the FDA may require such additional information on that change as it deems necessary.

If the FDA approves a petition permitting an applicant to vary one of the active ingredients of a generic drug from those of the listed combination drug, the ANDA must contain sufficient information to show that the active ingredients of the generic drug (including the varying active ingredient) are of the same pharmacological or therapeutic class as those of the listed drug. In addition, the differing generic drug must be expected to have the same therapeutic effect when administered to patients for an approved condition of use.

An example of such a change in one of the active ingredients that the FDA might find acceptable is the substitution of acetaminophen for aspirin in a combination product. Another example might be the substitution of one antihistamine for another. The active ingredient, which the applicant wishes to vary and which the FDA has granted a petition, must have been approved for safety and effectiveness or must not be within the requirements of section 201(p) of FFDCA.[10]

Certification of invalidity of noninfringement of a patent

When an applicant certifies that any product or controlling use patent is invalid or will not be infringed, paragraph (2)(B) requires that it must give notice of such certification to either the owner of the patent or the representative of the patent owner that was designated when the patent information was submitted under section 505(b) or (c) of the FFDCA. The FDA may, by regulation, establish a procedure for designating in the NDA the representative of the patent owner. In addition, notice of the certification must be given to the holder of the approved New Drug Application (NDA) for the drug which is claimed by a product patent or the use of which is claimed by a use patent.

This notice must be given simultaneously with the submission of an ANDA. The Committee does not intend that applicants be permitted to circumvent this notice requirement by filing sham ANDA's or ANDA's which are substantially incomplete. The Committee intends that the applicant must have made a good faith effort to meet the requirements set forth in paragraph (2)(A) regarding the contents of an ANDA.

While the Committee does not intend that failure to include a minor piece of information in an ANDA vitiates the effectiveness of the notice required under paragraph (2)(B), an ANDA must in-

[10] 21 U.S.C. 321(p). For example, a drug marketed prior to 1938 and unchanged is a "grandfathered drug" and thus not within the scope of the definition of "new drug" set forth in section 201(p) of the FFDCA. Another example of a drug outside the scope of section 201(p) is a product that is generally recognized as safe and effective and that has been used to a material extent or for a material time.

clude the results of any required bioavailability or bioequivalence tests. Failure to include the results of such tests when required will void the effectiveness of any notice under paragraph (2)(B). Notice must then be given again when an ANDA with any required bioavailability or bioequivalence data is submitted to the FDA.

When the applicant gives notice of the certification of patent invalidity or non-infringement, the notice must state that an ANDA has been submitted to obtain approval of the drug to engage in the commercial manufacture, use or sale of the generic drug before the expiration of the patent which has been certified as invalid or non-infringed.

If an ANDA is amended after submission to include a certification that a product patent or controlling use patent is invalid or not infringed, then the notice of such certification must be given to the appropriate parties when the amended application is submitted.

Grounds for disapproval of an ANDA

Paragraph (3) provides that the FDA shall approve an ANDA except in one of the following circumstances.

First, the FDA shall not approve an ANDA if the methods used in, or the facilities and controls used for, the manufacture, processing and packing of the generic drug are inadequate to assure and preserve its identity, strength, quality and purity.

Second, an ANDA shall not be approved if it does not contain adequate information to show that each of the conditions for use for the generic drug have been previously approved for the listed drug. If an ANDA includes a condition for use for which the listed drug has not been approved, then the generic drug may not be approved.

Third, an ANDA must be disapproved if the active ingredient of the generic drug is not the same as that of the listed drug and the listed drug has only one active ingredient. An ANDA must also be disapproved if any of the active ingredients in the generic drug are not the same as those of the listed drug unless a petition regarding a change in one of the active ingredients has been granted. If the listed drug is a combination product and a petition permitting a change in one of the active ingredients in the generic drug has been granted, then the ANDA must be disapproved if the other active ingredients of the generic drug are not the same as those of the listed drug. Further, ANDA must be disapproved in such a circumstance if the different active ingredient in the generic drug is not a listed drug or if the different active ingredient is a drug within the requirements of section 201(p) of the FFDCA.

Fourth, an ANDA for a drug which is the same must be disapproved if it does not show that the route of administration, dosage form, or strength of the generic drug are all the same as those of the listed drug. If the route of administration, dosage form, or strength of the generic drug differs from that of the listed drug, an ANDA must be disapproved if no petition regarding the change was granted.

Fifth, an ANDA must be disapproved if the generic drug differs from the listed drug and a petition regarding the change has been

granted, but the ANDA does not contain all of the additional information that the FDA required in granting the petition.

A sixth ground requiring disapproval of an ANDA for a generic drug whose active ingredients are the same as those of the listed drug is that there is unsufficient information to show that the generic drug is bioequivalent to the listed drug. If a petition regarding a change in one of the active ingredients in a combination generic drug has been granted, then the ANDA must be disapproved if the application fails to show that the active ingredients of the generic drug are of the same pharmacological or therapeutic class as those of the listed drug. In addition, such an ANDA must be disapproved if it fails to show that the differing generic combination drug can be expected to have the same therapeutic effect as the listed combination product when administered to patients for an approved condition of use.

Seventh, an ANDA must also be disapproved if it fails to show that the proposed labeling for the generic drug is the same as that of the listed drug. Changes in the proposed labeling due to the fact that the generic drug is produced or distributed by a different manufacturer are not a grounds for disapproval. Similarly, changes in the proposed labeling of the generic drug because a petition regarding a change has been granted is not a grounds for disapproval.

Eighth, an ANDA must be disapproved if it or any other information before the FDA shows that the inactive ingredients of the generic drug are unsafe for use under the conditions prescribed, recommended, or suggested in the proposed labeling for the generic drug. An ANDA must also be disapproved if the composition of the generic drug is unsafe under approved conditions of use. For example, the composition of the generic drug might be unsafe because of the type or quantity of the inactive ingredient included or because of the manner in which the inactive ingredient was included.

Ninth, an ANDA may not be approved if the approval of the listed drug has been withdrawn or suspended for reasons of safety or effectiveness under section 505(e) (1)-(4) of the FFDCA.[11] The ANDA may also not be approved if the FDA determines that the listed drug has been voluntarily withdrawn from the market for safety or effectiveness reasons. The Committee recognizes that the maker of a listed drug might withdraw it from the market without specifying the reason or without articulating safety or effectiveness concerns. For this reason, the Committee authorized the FDA to examine whether safety or effectiveness concerns were one of the reasons for the voluntary withdrawal of the drug from the market. IF the FDA so finds, then an ANDA for a generic version of that drug may not be approved.

Tenth, an ANDA may not be approved if it does not meet any of the requirements set forth in paragraph (2)(A). For example, an ANDA that does not contain the certifications regarding patents required in paragraph (a)(A)(vii) cannot be approved.

Last, an ANDA may not be approved if it contains any untrue statement of material fact.[12]

[11] 21 U.S.C. 352(e)(1)-(4).
[12] See Untrue statements in application, 21 C.F.R. 314.12 (1982).

Approval of an ANDA

Paragraph (4)(A) requires the FDA to approve or disapprove an ANDA within 180 days of initial receipt of the application. The Committee recognizes that extensions may be necessary so the bill permits extensions of this period for so long as the applicant and the FDA may agree upon.

Effectiveness of an ANDA approval

The Committee recognizes that some ANDA's will be submitted and ready for approval before the patent on the listed drug has expired. To deal with this situation and to assure that the FDA concerns itself solely with the safety and effectiveness of the generic drug, paragraph (4)(B) permits the FDA to approve an ANDA but make the approval effective at some later date when appropriate.

If the applicant certified in an ANDA that no patent information was supplied or that the relevant patents have expired, then the approval of the ANDA may be made effective immediately. If the applicant certified based upon the submitted patent information that the patent or patents would expire in one year, then an ANDA may be approved and the approval made effective in one year.

If the applicant certified that one or more of the product or controlling use patents were invalid or not infringed, then approval of the ANDA may be made effective immediately except in the following situation. If within 45 days after notice of the certification of invalidity or non-infringement is received, an action for patent infringement regarding one or more of the patents subject to the certification is brought,[13] then approval of the ANDA may not be made effective immediately. Instead, approval of the ANDA may not be made effective until 18 months after the notice of the certification was provided unless a district court has decided a case for patent infringement earlier. Once either of these events occurs and the approval of the ANDA becomes effective, then the FDA has discharged its statutory responsibility with respect to making the approval of the generic drug effective.

Each party to the action has an affirmative duty to reasonably cooperate in expediting the action. If the plaintiff breaches that duty, the court may shorten the 18 month period as it deems appropriate. If the defendant breaches that duty, the court may extend the 18 month period as it deems appropriate.

If the court decides that the patent is invalid or not infringed before the expiration of the 18 month period (or such shorter or longer period as the court decides), then the approval may be made effective on the date of the court decision. If the court decides that the patent is valid or infringed before the expiration of the 18 month period, then the approval may be made effective on such data as the court orders. The Committee wishes to emphasize that the court may not order an ANDA approved under this provision.

[13] The Committee recognizes that, in certain instances, the patent owner may agree with the certification of the applicant. For example, when the applicant certifies that patent No. 1 is invalid and patent No. 2 is not infringed, the patent owner may agree with the certification regarding patent No. 2. Then an action for patent infringement need only be brought with respect to patent No. 1.

These are times when approval of an ANDA may be made effective if the FDA has approved the ANDA.

This additional remedy permits the commencement of a legal action for patent infringement before the generic drug maker has begun marketing. The Committee believes this procedure fairly balances the rights of a patent owner to prevent others from making, using, or selling its patented product and the rights of third parties to contest the validity of a patent or to market a product which they believe is not claimed by the patent.

The provisions of this bill relating to the litigation of disputes involving patent validity and infringement are not intended to modify existing patent law with respect to the burden of proof and the nature of the proof to be considered by the courts in determining whether a patent is valid or infringed.

Concern has been expressed that permitting an applicant to market its drug at the conclusion of the 18 month period and possibly before the resolution of the patent infringement suit overturns the statutory presumption of a patent's validity. On the contrary, the Committee intends that a patent would have the same statutory presumption of validity as is afforded under current law.

In most instances, an ANDA will contain multiple certifications. The FDA should make approval of the ANDA effective upon the last certification. For example, if an ANDA contains a certification that a product patent is expired and a controlling use patent will expire in three years, then the FDA must make approval of the ANDA effective in three years. In the case where the patent certification is amended in an ANDA to allege invalidity or non-infringement of a patent, the FDA may not make the approval effective within the 45 day period that an action for patent infringement may be brought.

No action for a declaratory judgment regarding the patent at issue may be brought before the expiration of the 45 day period commencing with the provision of notice of the certification of patent invalidity or non-infringement. Any suit for declaratory judgment after the 45 day period must be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

Subsequent ANDA's certifying patent invalidity or noninfringement

If an ANDA certifying patent invalidity or non-infringement is filed subsequent to an ANDA for the same listed drug that has made the same certification of invalidity or non-infringement, paragraph (4)(B)(iv) provides that the approval of the subsequent ANDA may not be made effective sooner than 180 days after the previous applicant has begun commerical marketing, or the date on which the court holds the patent invalid or not infringed, whichever occurs first. In the event of multiple ANDA's certifying patent invalidity or non-infringement, the courts should employ the existing rules for multidistrict litigation, when appropriate, to avoid hardship on the parties and witnesses and to promote the just and efficient conduct of the patent infringement actions.[14]

[14] 28 U.S.C. 1407.

Disapproval of an ANDA

If the FDA decides to disapprove an ANDA, paragraph (4)(C) provides that the FDA must give the applicant notice of the opportunity for a hearing on the issue of the approvability of the ANDA. To avail itself of this hearing, the applicant must submit a written request within 30 days of the notice. If a hearing is requested, it must begin not later than 120 days after the notice. However, the hearing may be held later if both the applicant and the FDA agree. The hearing shall be conducted on an expedited basis. The FDA's order regarding the hearing shall be issued within 90 days after the date for filing final briefs.

Transition rule

Paragraph (4)(D)(i) provides that the FDA may not make effective the approval of an ANDA for a drug including an active ingredient (including any ester or salt of the active ingredient) which was approved for the first time in an NDA between January 1, 1982 and the date of enactment of this bill until 10 years after the date of approval of the NDA. For example, if active ingredient X was approved in a drug for the first time in 1983, when the approval of an ANDA for a drug containing active ingredient X could not be made effective until 1993.

Unpatentable drugs

If the active ingredient (including any ester or salt of the active ingredient) of a drug is approved for the first time in an NDA after the enactment of this bill, then paragraph (4)(D)(ii) provides that the FDA may not make the approval of an ANDA for a drug which contains the same active ingredient effective until four years after the approval of the NDA if the following conditions are met.

First, the holder of the NDA must certify that no patent has ever been issued to any person for such drug or for a method of using such drug. Second, the holder must certify that it cannot receive a patent for such drug or for a method using such drug for any known therapeutic purpose. In determining whether a drug meets these two patent stipulations, the FDA may rely upon the certifications of the NDA holder.

If the FDA determines at any time during the four year period that an adequate supply of the drug will not be available, it may make the approval of an ANDA effective before the expiration of the four year period. The FDA may also make the approval of an ANDA for such drug effective before the four year period if the holder of the NDA consents.

Withdrawal or suspension of listed drug's approval

Paragraph (5) provides that the approval of an ANDA is withdrawn or suspended if approval of the listed version of the generic drug has been withdrawn or suspended for safety or effectiveness reasons as set forth in section 505(e) (1)–(4) of the FFDCA. The approval of an ANDA is also withdrawn or suspended if it refers to a drug whose approval is withdrawn or suspended under section 505(j)(5) of the FFDCA. In addition, the approval of an ANDA is withdrawn or suspended if the FDA determines that the listed

drug has been voluntarily withdrawn from sale due to safety or effectiveness concerns.

The Committee recognizes that the maker of a listed drug might withdraw it from the market without specifying the reason or without articulating safety or effectiveness concerns. For this reason, the Committee authorized the FDA to examine whether safety or effectiveness concerns were one of the reasons for the voluntary withdrawal of the drug from the market. If the FDA so finds, then the approval of an ANDA for a generic version of that drug must be withdrawn or suspended.

The ANDA must be withdrawn or suspended from sale for the same period as the approval of the drug to which it refers has been withdrawn or suspended. When the listed drug has been voluntarily withdrawn from the market and the FDA has determined that the listed drug was withdrawn due to safety or effectiveness reasons, then the approval of the ANDA must be withdrawn until such time as the FDA determines that the listed drug was not withdrawn from sale for safety or effectiveness reasons.

Listings of drugs

Within 60 days after enactment of this bill, Paragraph (6) requires the FDA to publish and to make available a list of drugs eligible for consideration in an ANDA. The list must include the official and proprietary name of each drug that has been approved for safety and effectiveness prior to the date of enactment of the bill. The list must be in alphabetical order. If the drug was approved after 1981, the list must include the date of approval of the drug and the NDA number. Third, the list must specify whether in vitro or in vivo bioequivalence studies, or both, are required for ANDA's.

At 30-day intervals, the FDA must update the list to include drugs that have been approved for safety and effectiveness after enactment of H.R. 3605 and drugs approved in ANDA's under this subsection. In addition, the FDA must integrate into the list patent information submitted under sections 505 (b) and (c) of the FFDCA as it becomes available.

A drug approved for safety and effectiveness under section 505(c) or under subsection (j) shall be considered as published and thus eligible for approval in an ANDA on the date of its approval or the date of enactment, whichever is later.

Paragraph (6)(C) provides a drug may not be listed as eligible for consideration in an ANDA if the approval of the pioneer drug is withdrawn or suspended for safety or effectiveness reasons as set forth in section 505 (e)(1)-(4) of the FFDCA or if approval of the generic drug was withdrawn or suspended under Section 505(j)(5) of the FFDCA. In addition, a drug may not be listed if the FDA determines that the drug has been voluntarily withdrawn from sale due to safety or effectiveness concerns. If such a drug has already been listed, then it must be immediately removed from the list.

The Committee recognizes that the maker of a listed drug might withdraw it from the market without specifying the reason of without articulating safety or effectiveness concerns. For this reason, the Committee authorized the FDA to examine whether safety or effectiveness concerns were one of the reasons for the voluntary withdrawal of the drugs from the market. If the FDA so finds, then

the drug may not be listed. Persons adversely affected by this decision may seek judicial review under Title 5 of the United States Code.

A drug may not be listed as long as its approval is withdrawn or suspended. If the drug has been voluntarily withdrawn from the market, then the drug may not be listed until the FDA determines that the drug was not withdrawn from sale for safety or effectiveness reasons. A notice regarding the removal of any drug from the list must be published in the Federal Register.

Bioavailability and bioequivalence studies

As used in this bill, the term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.[15]

A drug shall be considered bioequivalent to a listed drug if the rate and extent of absorption of the generic drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses. A generic drug shall also be considered to be bioequivalent to a listed drug if the extent of absorption of the generic drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the generic drug is intentional, is reflected in the proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.[16]

Section 102

Section 102 of the bill requires that certain patent information be filed with all new NDA's and with all NDA's previously filed but not yet approved. Pending and future NDA's may not be approved unless they contain the appropriate patent information. The FDA shall publish the patent information upon approval of the NDA.

This section also requires that any previously approved NDA be amended within 30 days of enactment of this bill to include certain patent information. The FDA shall publish the patent information upon its submission. An NDA may be revoked if the patent information available is advisable and is not filed within 30 days after receipt of a written notice from the FDA specifying the failure to provide the patent information.

The patent information to be filed includes the patent number and the expiration date of any patent which claims the drug in the NDA or which claims a method of using such drug with respect to which a claim of patent infringement could reasonably be asserted

[15] See Definition of Bioavailability, 21 C.F.R. 320.1(a) (1982).
[16] See Definition of Bioequivalent Drug Products, 21 C.F.R. 320.1(e) (1982).

if a person not licensed by the owner engaged in the manufacture, sale or use of the drug. Patents which claim a method of manufacturing such drug are not required to be submitted.

Finally, section 102 makes a number of technical changes.

Section 103

Section 103 amends section 505(b) of the FFDCA to require an applicant filing a Paper NDA's for a listed drug under section 505(j)(6) to make the same certifications regarding patents as mandated in the filing of ANDA's under new subsection (j) of the FFDCA. In addition, the FDA must make approvals for such Paper NDA's effective under the same conditions that apply to ANDA's submitted under subsection (j). Finally, section 103 applies the 10 year transition rule and the 4 year unpatentable substances rule to Paper NDA's.

Paper NDA's

Paper NDA's are defined as any application submitted under section 505(b) of the FFDCA in which the investigations relied upon by the applicant to show safety and effectiveness were not conducted by or for the applicant and the applicant has not obtained a right of reference or use from the person who conducted the studies or for whom the studies were conducted.

Patent certifications in paper NDA's for listed drugs

When a Paper NDA's is submitted for a listed drug under section 505(j)(6), it must include a certification by the applicant regarding the status of certain patents applicable to the listed drug if such information has been provided to the FDA. With respect to all product patents which claim the listed drug and all use patents which claim an indication for the drug for which the applicant is seeking approval (hereafter described as a controlling use patent), the applicant must certify, in his opinion and to the best of his knowledge, as to one of four circumstances.

First, the applicant may certify that the patent information required under sections 505 (b) and (c) has not been submitted if that is the case. Second, if appropriate, the applicant may certify that one or more of the product or controlling use patents provided have expired. Third, the applicant may certify when appropriate that one or more of the product or controlling use patents will expire at some specified date in the future. When the applicant makes these certifications, it must rely upon the patent information supplied to the FDA. Last, an applicant may certify if applicable that one or more of the product or controlling use patents are invalid or will not be infringed.

The Committee recognizes that in some instances an applicant will have to make multiple certifications with respect to product and controlling use patents. For example, if the product patent has expired and valid controlling use patent will not expire for three years, then the applicant must certify that one patent has expired and the other will expire in three years. The Committee intends that the applicant make the appropriate certification for each product and controlling use patent.

Every Paper NDA for a listed drug must also state, when applicable, that the applicant is not seeking approval for an indication which is claimed by any use patent for which it has not made a certification. For example, the listed drug may be approved for two indications. If the applicant is seeking approval only for indication No. 1, and not indication No. 2 because it is protected by a use patent, then the applicant must make the appropriate certifications and a statement explaining that it is not seeking approval for indication No. 2.

Certification of invalidity or noninfringement of a patent

When an applicant certifies that any product or controlling use patent is invalid or will not be infringed, section 505(b)(3) requires that it must give notice of such certification to either the owner of the patent or the representative of the patent owner that was so designated when the patent information was submitted under section 505 (b) or (c) of the FFDCA. The FDA may, by regulation, establish a procedure for designating in the NDA the representaitve of the patent owner. In addition, notice of the certification must be given to the holder of the approved New Drug Application (NDA) for the drug which is claimed by the product patent or the use of which is claimed by the use patent.

This notice must be given simultaneously with the submission of a Paper NDA. The Committee does not intend that applicants be permitted to circumvent this notice requriement by filing sham Paper NDA's or Paper NDA's which are substantially incomplete. The Committee intends that the applicant must have made a good faith effort to meet the requirements regarding the contents of a Paper NDA as set forth in section 505(b) of FFDCA.

When the applicant gives notice of the certification of invalidity or non-infringement, the notice must state that a Paper NDA has been submitted to obtain approval of the drug to engage in the commercial manufacture, use or sale of the generic drug before the expiration of the patent which has been certified as invalid or non-infringed.

If a Paper NDA is amended after submission to include a certification that a product patent or controlling use patent is invalid, then the notice of such certification must be given to the appropriate parties when the amended application is submitted.

Effectiveness of approval of a paper NDA for a listed drug

The Committee recognizes that some Paper NDA's for listed drugs will be submitted and ready for approval before the patent on the listed drug has expired. To deal with this situation and to assure that the FDA concerns itself solely with the safety and effectiveness of the generic drug, section 505(c)(3) requires the FDA to approve a Paper NDA but make the approval effective at some later date when appropriate.

If the applicant certified in the Paper NDA that no patent information was supplied or that the relevant patents have expired, then the approval of the Paper NDA may be made effective immediately. If the applicant certified based upon the submitted patent information that the patent would expire in one year, then the

Paper NDA may be approved and the approval made effective in one year.

If the applicant certified that one or more of the product of controlling use patents were invalid or not infringed, then approval of the Paper NDA may be made effective immediately except in the following situation. If within 45 days after notice of the certification of invalidity or non-infringement is received, an action for patent infringement regarding one or more of the patent subject to the certification is brought,[17] then approval of the Paper NDA may not be made effective immediately. Instead, approval of the Paper NDA may not be made effective until 18 months after the notice of the certification was provided.

Each party to the action has an affirmative duty to reasonably cooperate in expenditing the action. If the plaintiff breaches that duty, the court may shorten the 18 month period as it deems appropriate. If the defendent breaches that duty, the court may extend the 18-month period as it deems appropriate.

If the court decides that the patent is invalid or not infringed before the expiration of the 18-month period (or such shorter or longer period as the court decides), then the approval may be made effective on the date of the court decision. If the court decides that the patent invalid or infringed before the expiration of the 18 month period, then the approval may be made effective on such date as the court orders. The Committee wants to emphasize that the court may not order the Paper NDA approved. These are times when the approval of a Paper NDA may be made effective if the FDA has completed its review of the Paper NDA.

No action for a declaratory judgment regarding the patent at issue may be brought before the expiration of the 45 day period commencing with the provision of notice of the certification of patent invalidity or non-infringement. After the 45 day period, any suit for declaratory judgment regarding the patent at issue must be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

Transition rule

Section 505(c)(3)(D)(i) provides that the FDA may not make effective the approval of a Paper NDA for a drug which contains an active ingredient (including any ester or salt of the active ingredient) which was approved for the first time in an NDA between January 1, 1982 and the date of enactment of this bill until 10 years after the date of approval of the NDA. For example, if active ingredient X was approved in a drug for the first time in 1983, then the approval of a Paper NDA for a drug containing active ingredient X could not be made effective until 1993.

Unpatentable drugs

If the active ingredient (including any ester or salt of the active ingredient) of a drug is approved for the first time in an NDA after

[17] The Committee recognizes that in certain instances, the patent owner may agree with the certification of the applicant. For example, when the applicant certifies that patent No. 1 is invalid and patent No. 2 is not infringed, the patent owner may agree with the certification regarding patent No. 2. Then an action for patent infringement need only be brought with respect to patent No. 1.

the enactment of this bill, then section 505(c)(3)(D)(ii) provides that the FDA may not make the approval of a Paper NDA for a drug which contains that active ingredient effective until four years after the approval of the NDA if the following conditions are met.

The holder of the NDA must certify that no patent has ever been issued to any person for such drug or for a method of using such drug. Further, the holder must certify that he cannot receive a patent for such drug or for a method using such drug for any known therapeutic purpose.

If the FDA determines at any time during the four year period that an adequate supply of the drug will not be available, it may make the approval of a Paper NDA effective before the expiration of the four year period. The FDA may also make the approval of a Paper NDA for the drug effective before the four year period if the holder of the NDA consents.

Section 104

Section 104 amends section 505 of the FFDCA to add a new subsection (1). This new subsection provides that safety and effectiveness information that has been submitted in an NDA and which has not been previously disclosed to the public shall be made available to the public upon request under the following circumstances unless extraordinary circumstances are shown.

First, the safety and effectiveness information and data shall be disclosed upon request if the NDA has been abandoned. Second, such information and data shall be made available upon request if the FDA has determined that the NDA is not approvable and all legal appeals have been exhausted. Third, the data and information shall be released upon request if the approval of the NDA under section 505(c) of the FFDCA has been withdrawn and all legal appeals have been exhausted. Fourth, such information and data shall be released upon request if the FDA has determined that the drug which is the subject of the NDA is not a new drug.

These conditions under which such safety and effectiveness data shall be released upon request, unless extraordinary circumstances are shown, are merely a restatement of the current regulation. The Committee intends that all terms in new section 505(1) be given the same meaning that they have in the regulation.[18] It is not the intent of the Committee to alter the rights of the public under the Freedom of Information Act.

The Committee does intend, however, to clarify the interpretation of 21 C.F.R. 314.14(f)(5).[19] In this circumstance, safety and ef-

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[18] See Confidentiality of data and information in a new drug application (NDA) file, 21 C.F.R. 314.14(f)(1)-(4) (1982).

[19] 21 C.F.R. 314.14(f)(5) provides:

"(5) A final determination has been made that the drug may be marketed without submission of such safety and/or effectiveness data and information."

The Committee was concerned that this provision of the regulation might be interpreted as permitting the disclosure of such information and data upon enactment of this bill. This is because all drugs approved for safety and effectiveness prior to enactment of this bill are deemed listed and thus eligible for consideration in an ANDA upon enactment of the bill. The Committee wished to avoid any possibility that listing of a drug under this bill would be deemed a final determination that the drug could be approved without the submission of safety and effectiveness information.

fectiveness data and information may be released upon the effective date of the first approval of an ANDA for such drug under new subsection (j) of section 505 of the FFDCA. Further, the information and data may be released on the date upon which an approval of an ANDA could be made effective if an ANDA had been submitted. The Committee recognizes that an ANDA may not be submitted for all drugs that are eligible for approval as generics. To deal with that possibility, the Committee intends to make available this data when the approval of an ANDA would have become effective.

The Committee does not intend that any safety and effectiveness data and information be released pursuant to this section during the 30 day perioid after enactment of this bill when patent information must be submitted under section 505(b) or (c). Otherwise, ANDA's filed during that period could be approved effective immediately, thus allowing for the disclosure of safety and effectiveness information and data for those drugs.

The Committee also does not intend that safety and effectiveness data and information be released under this section if an ANDA challenging the validity of a patent is approved before there has been a court decision holding the patent invalid and if the NDA holder brings an action to restrain the disclosure.

Finally, except as provided in this section, the Committee does not intend to change other regulations regarding Freedom of Information Act requests, trade secrets, and confidentiality of IND, NDA and master file safety and effectiveness information and data.

Section 104 also adds a new subsection (m) to Section 505 of the FFDCA. This provision clarifies that any reference to patent information in Section 505 applies only to patents issued by the Patent and Trademark Office of the Department of Commerce. It does not include any patents issued by foreign governments.

Section 105

Section 105(a) of the bill requires the FDA to promulgate such regulations as are necessary to implement new subsection (j). These regulations must be promulgated in accordance with the informal rulemaking requirements of Title 5 of the United States Code and not later than one year after enactment of this bill.

Section 105(b) of the bill establishes an interim procedure for approving ANDA's for post-1962 drugs until the final implementing regulations are promulgated. During the period after enactment of this bill and until the promulgation of regulations by the FDA, ANDA's for listed post-1962 drugs may be submitted in accordance with the current regulations applicable to pre-1962 pioneer drugs.

To the extent that there are inconsistencies between the current regulations and this Act, the FDA shall follow this Act. Under no circumstances may the FDA approve an ANDA or Paper NDA under this interim procedure for a drug that is eligible for four or ten years of market exclusivity except in accordance with those provisions.

mercial marketing, but it must be the first time a product made by the claimed process has been approved.

The Committee's bill requires extensions to be based on the first approval of a product because the only evidence available to Congress showing that patent time has been lost is data on so-called class I, new chemical entity drugs. These drugs had been approved by the Food and Drug Administration (FDA) for the first time. An exception was allowed for products made through recombinant DNA because this innovative, new technique is being employed to improve already approved drugs.

Paragraph (8) addresses the circumstances where two different approved products are the subject of the same patent. An extension would be granted only for the first approved product which has been the subject of a regulatory review period.

Conditions of extension applicable to product and use patents

Paragraph (4) of section 156(a) describes conditions which are applicable to product and use patents only.

Paragraph (4)(A) permits such a patent to be extended if two requirements are met. The first is that the approved product is not claimed in another product patent which has been extended or which as an earlier issuance date. The second is that the approved product and the use for which the product is approved are not identically disclosed or described in another product or use patent which has been extended or which has an earlier issuance date. The phrase "identically disclosed or described" is intended to have the same meaning which it has under current patent law.[20]

The policy which the Committee seeks to implement in paragraph (4)(A) is, in brief, that the first patent (1) which claims the approved product, in the sense that the approved product would infringe a claim of that patent, or (2) which fully discloses that product and its approved use, is the patent which should be rewarded with an extension. For example, if the approved product is the subject of several patents as a result of filing continuation, continuation-in-part, divisional or otherwise related patent applications, each of which discloses the approved product and its approved use, then only the earliest issued patent is eligible for an extension.

Paragraph (4)(B) is an exception to the rule in paragraph (4)(A) for certain product patents. If two conditions are met, a product patent can be extended even though the approved product is also claimed in another product patent which has been extended or which has an earlier issuance date. First, the product patent which was issued earlier or previously extended cannot identically disclose or describe the approved product. Second, the holder of each of the two product patents must never have been and must never become the holder of the other patent. In this paragraph, the term "holder" is any person who owns the patent or is an exclusive licensee of the owner. This exception was included to prevent an earlier issued patent which claims a broad genus of compounds from blocking the possible extension of a later issued patent claiming a

[20] The phrase "identically disclosed or described" in used in 35 U.S.C. 103 to set forth the conditions of 35 U.S.C. 102.

specific member of that genus where neither patent holder had a choice as to which patent to extend.

Conditions of extension applicable to process patents

Paragraph (5) of section 156(a) describes conditions which are applicable to process patents only.

Paragraph (5)(A) permits a process patent, which does not primarily utilize recombinant DNA in the manufacture of the approved product, to be extended if two conditions are met. First, there can not be any issued product patent which claims the approved product or any issued use patent which claims a method of using the approved product for any known therapeutic use. And, second, there can not be an earlier issued process patent, which does not primarily utilize recombinant DNA and which claims a method of manufacturing the approved product.

Paragraph (5)(B) permits a process patent, which primarily utilizes recombinant DNA in the manufacture of the approved product, to be extended if several conditions are met. First, the holder of the process patent can not hold a product patent claiming the approved product or a use patent claiming a method of using the approved product. Second, there can not be an ownership or control interest, either directly or indirectly, between the holder of the process patent and the holder of any product patent claiming the approved product or the holder of any use patent claiming a method of using the approved product. Third, there can not be any earlier issued process patent which claims a method of manufacturing the approved product by primarily utilizing recombinant DNA.

The Committee's bill establishes separate rules for process patents which do not use recombinant DNA because the discovery of such a new process for making an existing product does not warrant the same reward of patent extension as does the discovery of a new product. An extension for the process patent is appropriate only when there are no product or use patents. On the other hand, when recombinant DNA technology is the essential and predominant technique used in making an improved version of an existing product, the Committee believes that this new and important innovation should be rewarded.

Section 156(b)

Rights to be extended

Except for the limitations described below with respect to the scope of the patent claims, all provisions of the patent law apply to the patent during the period of extension. The limitations are as follows: (1) When a product patent claiming the approved product is extended, the holder's rights are limited to any use of the approved product which was approved before the expiration of the extended term of the patent under the provision of law under which the applicable regulatory review period occurred.

(2) When a use patent claiming a method of using the approved product is extended, the holder's rights are limited to any use of the approved product which: (a) is claimed in the use patent, and (b) was approved before the expiration of the extended term of the

patent under the provision of law under which the applicable regulatory review period occurred.

(3) When a process patent claiming a method of manufacturing the approved product is extended, the holder's rights are limited to the method of manufacturing which: (a) is claimed in the process patent, and (b) is used to make the approved product.

Section 156(c)

Period of extension

Section 156(c) specifies the rules by which the length of the period of extension is determined. The calculation made under these rules is further limited by the requirements of section 156(g)(4).

Under section 156(c), the length of the extension is based on the length of the regulatory review period in which the approved product was approved. The definition of the various regulatory review periods is in sections 156(g) (1)–(3). All regulatory review periods are divided into a testing phase and an agency approval phase.

The regulatory review period which occurs after the patent to be extended was issued is eligible to be counted towards extension in accordance with the following calculation. First, each phase of the regulatory review period is reduced by any time that the applicant for extension did not act with due diligence during that phase. (The determination of lack of due diligence is made under section 156(d).) Second, after any such reduction, one-half of the time remaining in the testing phase would be added to the time remaining in the approval phase to comprise the total period eligible for extension. Third, all of the eligible period can be counted unless to do so would result in a total remaining patent term of more than fourteen years. For example, if an approved drug product which is eligible for five years of extension had ten years of original patent term left at the end of its regulatory review period, then only four of the five years could be counted towards extension.

The additional limitation on the period of extension is found in section 156(g)(4). That section provides different maximum periods of extension depending on whether the approved product was developed before or after the date of enactment.

Under that section, the total period of regulatory review which can be counted towards extension would not exceed five years when: (1) the patent to be extended was issued after the date of enactment of this bill; or (2) the patent was issued before the date of enactment, but the approved product's regulatory review period had not begun on the date of enactment. The total period of eligible regulatory review would not exceed two years when: (1) the patent to be extended was issued before the date of enactment; and (2) the approved product's regulatory review period had begun before the date of enactment but the product had not been approved by that date. If any action was taken before the date of enactment which initiated the testing phase of the regulatory review period, then the applicant would not be eligible for the five year rule by discontinuing activity and then initiating a new regulatory review period after the date of enactment.

The Committee established different maximum periods of extension to provide greater incentive for future innovations. By extending patents for up to five years for products developed in the future, and by providing for up to fourteen years of market exclusivity, the Committee expects that research intensive companies will have the necessary incentive to increase their research and development activities.

Section 156(d)

Application for extension

To obtain an extension, the patent owner or its agent would submit an application to the Commissioner of Patents and Trademarks within 60 days of approval of the approved product. The application would contain the information described in subparagraphs (A)–(G) of section 156(d)(1). The applicant would be subject to any disclosure requirements prescribed by the Commissioner. The Committee expects that those requirements would subject the applicant to at least the same duty of disclosure, and the penalties and loss of rights for violation of the duty of disclosure, which governs all patent application proceedings before the Patents and Trademarks Office.

Within 60 days of the submission of an application, the Commissioner would notify the Secretary of Health and Human Services, or the Secretary of Agriculture, as appropriate, to review the dates contained in the application for the regulatory review period. Within 30 days, the appropriate Secretary would make a determination as to those dates, notify the Commissioner of them, and publish them in the Federal Register.

Determination of due diligence (section 156(d)(2)(B))

The Committee's bill provides a definition of due diligence at Section 156(d)(3). It is "that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period."

A petition may be submitted by any interested person to the appropriate Secretary requesting a determination of whether the applicant for extension acted with due diligence during the regulatory review period of the approved product. The petition must be submitted within 180 days of the publication by the Secretary of a determination of the regulatory review period and must state claim that the applicant did not act with due diligence during some part of the regulatory review period. If the Secretary concludes from the information in the petition that there is reason to believe that the applicant failed to act with due diligence at some point in the regulatory review period, then the Secretary would make, within 90 days of the receipt of the petition and in accordance with regulations, a determination of whether the applicant acted with due diligence. The Secretary of HHS is prohibited from delegating the authority to make the determination to any office below that of the Commissioner of FDA.

While the bill places the burden on the petitioner to make the necessary showing, the Committee recognizes that the information

needed to make a final determination of due diligence is not available to the petitioner. To meet this burden of proof, the petitioner need not show conclusively that there was a lack of due diligence. Instead, the petitioner need only allege sufficient facts to merit an investigation by the Secretary. For example, it would be sufficient for the petitioner to demonstrate that human clinical trials did not begin for an unreasonably long period of time after the FDA granted permission to begin those trials or that the trials took an unreasonably long period of time. In those events, the Secretary would determine whether the delay was caused by a lack of due diligence on the part of the applicant.

After making the determination, the Secretary would notify the Commissioner of Patents and Trademarks and publish it in the Federal Register. Any interested person could request an informal hearing within 60 days of publication of the determination. If a timely request is made, the Secretary must hold such a hearing within 30 days, give notice of the hearing to the patent owner and any interested person, and provide such persons with an opportunity to participate. Within 30 days of the hearing, the Secretary must affirm or revise the determination, notify the Commissioner of Patents, and publish it in the Federal Register.

The Committee established a system for review of due diligence that requires the minimal amount of federal agency personnel time. The goal of the system is to assure that obvious delays during regulatory review, such as a prolonged period when human clinical trials on a drug product are not being conducted, are not counted towards patent extension. The system is not intended to cause a review of every action, but to identify significant periods of time when the loss of patent term resulted solely from the applicant's failure to pursue approval. Delays caused by the temporary unavailability of necessary testing facilities, or a scientific dispute involving tests required for approval or the interpretation of those tests, are examples of delays which can reasonably be expected to occur and would not be a basis for finding a lack of due diligence.

Section 156(e)

Determination on patent extension of the Commissioner of Patents and Trademarks

The Commissioner would make the final determination that a patent is eligible for extension under section 156(a), that the requirements of section 156(d) have been met, and that the period of extension will be the period prescribed in section 156(c). Once these findings are made, the Commissioner would be required to issue a certificate of extension to the applicant. The certificate would be recorded in the official file of the patent and be considered a part of the original patent.

The Commissioner's decision regarding a patent's eligibility for extension under the rules of section 156(a) may be based solely on the information contained in the application. The burden is on the applicant to show that all patents which are relevant to the eligibility determination have been considered and do not prevent the requested extension.

While the Commissioner would be responsible for evaluating the applicant's determination regarding the patents listed in the application, the Committee expects that most reviews would be ministerial in nature. Since the applicant is under a duty to disclose all relevant information (see section 156(d)(4)), the application should be so well documented that a substantive review by the Commissioner would usually not be necessary.

Expiration of a patent pending extension (section 156(e)(2))

It is possible that the original term of the patent for which extension is sought could expire before a final decision by the Commissioner to issue a certificate of extension. This might occur, for instance, because the determination of due diligence by the Secretary of HHS or Agriculture has not been completed.

In such circumstances, the Commissioner is required to determine whether the patent is eligible for extension under section 156(a), and if it is, to issue a certificate of extension for a period of up to one year. The length of this interim extension is discretionary with the Commissioner, but is intended to provide time for the completion of any outstanding requirements. If the Commissioner determined that subsequent interim extensions were necessary, and consistent with the objectives of section 156(e)(2), they could be granted as well. In no event could these interim extensions be longer than the maximum period of extension to which the applicant is thought to be eligible.

Section 156(f)

Definitions

The term "product" is defined in subsection (f)(1) to include drug products and medical devices, food additives and color additives subject to regulation under the Federal Food, Drug, and Cosmetic Act.

The term "drug product" is defined in subsection (f)(2) to mean the active ingredient of a new drug, antibiotic drug, new animal drug, or human or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and the Virus-Serum-Toxin Act), including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient. The human drugs included in this definition are both prescription and over-the-counter drugs.

The term "major health or environmental effects test" is defined in subsection (f)(3) to mean a test which is reasonably related to the evaluation of the health or environmental effects of a product, which requires at least six months to conduct, and the data from which is submitted to receive permission for commercial marketing or use. Periods of analysis or evaluation of test results are not to be included in determining if the conduct of a test required at least six months.

The term "informal hearing" is defined in subsection (f)(5) to have the same meaning as "prescribed for such term by section 201(y) of the Federal Food, Drug, and Cosmetic Act."

The term "patent" is defined in subsection (f)(6) to mean "a patent issued by the United States Patent and Trademark Office.

Section 156(g)

Definition of regulatory review period

The "regulatory review period" differs for each product that can be the subject of patent extension, but in all cases it is considered to have a testing phase and an agency approval phase.

In sections 156(g) (1)–(3) of the term "initially submitted" is used to describe the point in time when the testing phase is considered to be completed and the agency approval phase to have begun. This term is used instead of the term "filed," because an application is often not considered to be filed, even though agency review has begun, until the agency has determined that no other information is needed and a decision on the application can be made. For purposes of determining the regulatory review period and its component periods, an application for agency review is considered to be "initially submitted" if the applicant has made a deliberate effort to submit an application containing all information necessary for agency review to begin. The Committee recognizes that the agency receiving the application might decide it needs additional information or other changes in the application. As long as the application was complete enough so that agency action could be commenced, it would be considered to be "initially submitted".

Drug products (section 156(g)(1)

The regulatory review period for drug products is the sum of the periods: (1) beginning when an exemption under 505(i), 507(d), or 512(j) was granted or authority to prepare an experimental drug product under the Virus-Serum-Toxin Act was granted and ending when with the initial submission of an application for approval under section 351 of the Public Health Service Act, 505, 507, 512 of the Federal Food, Drug, and Cosmetic Act, or the Virus-Serum-Toxin Act; and (2) beginning when an application for approval was initially submitted under section 351 of the PHS, 505, 507, 512 of the FFDCA or the Virus-Serum-Toxin Act and ending when the application was approved.

Food and color additives (section 156(g)(2))

The regulatory review period for food and color additives is the sum of the periods: (1) beginning when a major health or environmental effects test for a food or color additive was initiated and ending when a petition requesting the issuance of a regulation for use of the additive was initially submitted; and (2) beginning when a petition for the issuance of a regulation was initially submitted and ending when the regulation became effective.

If permission for commercial marketing was delayed because objections were filed to the regulation, or if such permission was initially granted and later revoked before actual marketing began because objections were filed to the regulation, then the period described in (2) above would end when the objections were resolved and commercial marketing was permitted.

Medical devices (section 156(g)(3))

The regulatory review period for medical devices is the sum of the periods: (1) beginning when human clinical investigations are

commenced and ending when an application for approval was initially submitted; and (2) beginning when an application for approval was initially submitted and ending when the application was approved, or beginning when a notice of completion of a product development protocol was initially submitted and ending when the protocol was declared completed.

Limitations on the regulatory review period (section 156(g)(4))

A discussion of this section is contained in the earlier section 156(c) entitled "Period of Extension".

Section 156(h)

Fees for applications

The Commissioner of Patents and Trademarks is authorized to establish such fees as he determines appropriate to cover the entire cost of the Patents and Trademarks Office of receiving and acting upon applications for patent extensions.

Section 202 of the Bill

Section 202 creates a new section 271(e) in Title 35 of the United States Code, the Patent Law.

Patent infringement (section 271(e))

Section 271(e)(1) provides that it shall not be an act of infringement to make, use, or sell a patented invention solely for uses reasonably related to the development and submission of information under a federal law which regulates the approval of drugs. This section does not permit the commercial sale of a patented drug by the party using the drug to develop such information, but it does permit the commercial sale of research quantities of active ingredients to such party. The information which can be developed under this provision is the type which is required to obtain approval of the drug. A party which develops such information, but decides not to submit an application for approval, is protected as long as the development was done to determine whether or not an application for approval would be sought.

Section 271(e)(2) provides that it shall be an act of patent infringement to submit an ANDA for a drug (1) which is claimed in a valid product patent, or (2) a use of which is claimed in a valid use patent, if the purpose of submitting the ANDA is to get approval of the ANDA with an effective date prior to the expiration of such patents.

The purpose of sections 271(e)(1) and (2) is to establish that experimentation with a patented drug product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement. Since the Committee's Subcommittee on Health and the Environment began consideration of this bill, the Court of appeals for the Federal Circuit held that this type of experimentation is infringement.

In *Roche Products, Inc.* v. *Bolar Pharmaceutical Co., Inc.* —F.2d— (Fed. Cir., April 23, 1984), the Court of Appeals for the Federal Circuit held that the experimental use of a drug product prior to the

expiration date of a patent claiming that drug product constitutes patent infringement, even though the only purpose of the experiments is to seek FDA approval for the commercial sale of the drug after the patent expires. It is the Committee's view that experimental activity does not have any adverse economic impact on the patent owner's exclusivity during the life of a patent, but prevention of such activity would extend the patent owner's commercial exclusivity beyond the patent expiration date.

Article 1, Section 8, Clause 8 of the Constitution empowers Congress to grant exclusive rights to an inventor for a limited time. That limited time should be a definite time and, thereafter, immediate competition should be encouraged. For that reason, Title I of the bill permits the filing of abbreviated new drug applications before a patent expires and contemplates that the effective approval date will be the expiration date of the valid patent covering the original product. Other sections of Title II permit the extension of the term of a patent for a definite time provided certain conditions are met. There should be no other direct or indirect method of extending patent term.

Remedies for patent infringement (section 271(c) (3)-(4))

In an infringement action pursuant to this section, no injunctive or other relief could be granted to prohibit the activity which is permitted by section 271(e)(1).

The Committee expects that infringement actions pursuant to this section will only be brought in the instance described in section 271(e)(2), where a party submitting an abbreviated new drug application under Title I of this bill certifies that a patent is invalid or non-infringed and gives the required notice of that certification to the patent owner. In the event the patent is found to be valid and infringed, so that the act of infringement described in section 271(e)(2) has occurred, the remedies available to the court are three-fold.

If the infringing party has not begun commercial marketing of the drug, injunctive relief may be granted to prevent any commercial activity with the drug and the FDA would be mandated to make the effective date of any approved ANDA not earlier than the expiration date of the infringed patent. The injunction could not prohibit the infringing party from using ther information contained in the application to support the approval of the application at the later effective date. In the case where the ANDA had not been approved, the order would mandate the effective date of any approval to be not earlier than the expiration date of the infringed patent. In the case where an ANDA had been approved, the order would mandate a change in the effective date.

If the infringing party has begun commercial marketing of the drug, damages and other monetary relief and injunctive relief may be awarded for the infringement and to prevent further infringement. In addition, the FDA would be mandated to change the effective date of the approved ANDA to the expiration date of the infringed patent.

Section 203 of the Bill

Section 203 adds a new provisions to section 282 of Title 35, United States Code.

Defenses to patent infringement (section 282)

The new provision in section 282 provides that an improper grant of patent extension, or any portion thereof, because of a material failure by the applicant or by the Commissioner of Patents and Trademarks to comply with the requirements of section 156, is a defense in any action involving the infringement of the patent during the patent extension. Any failure by the applicant to comply with the requirements of section 156 would be considered material only if the failure would have changes the decision to grant the extension or the length of the extension. Any failure by the Commissioner to comply with the requirements of section 156 would be considered material unless the Commissioner failed to meet a time deadline.

Under this provision, a court which found some portion of the extension to be improperly granted would not invalidate the entire patent extension. For example, if the Commissioner made a mathematical error that resulted in a five year extension instead of the four year extension to which the applicant was entitled, the court would invalidate only that portion of the patent extension improperly granted.

Implicit in section 156 is a directive to the Commissioner to correct any failure on his part that resulted in the funding of invalidity of a patent extension or any portion of it. The new provision does not create any cause of action under the Tort Claims Act against that Commissioner or any Patents and Trademarks Office employee involved with the extension.

In an action involving this new provision, the determination regarding due diligence made under section 156(d)(2) is not subject to review.

AGENCY VIEWS

Agency comments were submitted by the Food and Drug Administration during the July 15, 1983, hearing of the Subcommittee on Health and the Environment.

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MINORITY VIEWS OF MR. BLILEY

INTRODUCTION

H.R. 3605, as reported by the Committee, is a bill described by its proponents as having something for everyone—restoration of patent terms for products subject to elaborate premarket approval requirements to provide incentives for pharmaceutical research and facilitation of approval of generic drugs by the Food and Drug Administration under abbreviated application procedures to increase drug price competition. The objectives of this legislation are salutary and have the support of all interested parties. In my view, however, the legislation fails to achieve a proper balance between these two objectives.

Instead of providing an appropriate patent term for pharmaceuticals by restoring the time devoted to periods of "regulatory review," the bill strictly limits the types of patents eligible for term restoration and the conditions and length of the restoration period. In short, the patent term restoration provisions of this bill are largely illusory. Moreover, the bill would overrule a decision of the highest patent court in this country and thereby allow generic drug companies to use a patented product during the term of the patent. This is a substantial diminution of the rights currently held by the owner of the patent and has serious constitutional and policy implications which have not been considered by the Committee. The patent provisions of this bill also encourage patent "jumping" and litigation over the validity of patents.

The abbreviated new drug application (ANDA) provisions of this bill are equally troublesome. For example, the bill has substantial adverse effects on the resources and legal authority of the Food and Drug Administration, which has expressed some of its concerns about the bill in a document entitled "Technical Comments on June 2 Discussion Draft ANDA/Patent Term Restoration Legislation," largely to no avail. Many Members of the Congress and various prestigious academic and study groups have explored recently the need for faster approvals of innovative and medically necessary new drugs. The need to accelerate the approval of new drugs has been acknowledged by nearly everyone, including the FDA. It is astonishing, in light of the widely held view that the new drug approval process takes too long, that the Committee reported H.R. 3605, which imposes substantial new administrative and resource burdens on the FDA which will almost certainly have the effect of forcing FDA to divert resources from the review and approval of new therepeutic entities to the review and approval of copies of already-available drugs.

I am deeply concerned that in its haste to report this lengthy and complex bill, the Committee has failed to consider fully and adequately its effects—intended and unintended, desirable and un-

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desirable—in either hearings or markup. H.R. 3605 is a significant piece of legislation with important implications for consumers, re-

search-based pharmaceutical companies, generic drug companies and for the FDA. In point of fact, however, the Committee has reported a highly significant and lengthy bill without any hearings having been held on it in either the Health Subcommittee or in the full Committee. It is no answer to say that the bill is the result of lengthy negotiations between the brandname and generic drug industry trade associations. Many significant interests, including the patent bar, have never been heard from. Moreover, many of the highly innovative and research-oriented pharmaceutical firms have serious reservations about the bill as reported as apparently, does the FDA.

H.R. 3605 is an admirable beginning to the process of striking an appropriate balance among a variety of competing and important policy objectives. There is ample time for, and a compelling need to, consider, revise and improve upon the bill. In my view, the bill should be returned to the Health Subcommittee for further hearings and amendment, rather than being reported in haste by this Committee. Further, because this Committee lacks expertise in patent matters, the Committee is not qualified to evaluate the patent provisions of H.R. 3605. We do this institution a disservice by hastily reporting on the very day of introduction, a complex bill outside the expertise of the Committee after a "markup" that lasted barely thirty minutes.

In the next sections of my views, I describe in greater detail the significant areas in which this bill is deficient.

I. TITLE I—ABBREVIATED NEW DRUG APPLICATIONS

A. Limits on FDA authority

Both the research-based pharmaceutical companies which favor amendments to H.R. 3605 and the FDA itself have identified ways in which the bill unwisely restricts FDA's authority to ensure that all drugs are demonstrated to be safe and effective.

First, the bill expressly prohibits FDA from requesting data on the safety or efficacy of certain generic drugs, even where such data are needed to fulfill the FDA's public health responsibilities. Although one would not anticipate that FDA would need to resort to this authority very often, I believe it is a fundamental mistake to deprive the FDA of the authority simply because it is assumed that it will need to exercise it only rarely.

Second, it has been the longstanding policy of FDA to require that persons seeking to market drugs combining two or more active ingredients demonstrate that the combination itself, as opposed to the active ingredients individually, be shown to be safe and effective. FDA's authority to require this proof has been upheld by the courts. Without explanation or hearing, H.R. 3605 would overrule this policy and limit FDA's consideration of safety and efficacy to the individual active ingredients of combination drugs. I do not believe that the Congress should provide for the approval of new combinations of drugs without requiring the applicant to demonstrate that the combination is safe and effective. The public health should not be compromised in this fashion.

B. Resource implications

The review and approval by FDA of new pharmaceuticals—often innovative and highly desirable developments essential to the health of our citizens—is perhaps the most important function that the Congress has given to the FDA. The American people and the Members of the Congress rightly expect that this function be performed competently and expeditiously. New drugs are often inexpensive ways to cure life-threatening or debilitating diseases. Unnecessary delay in making these drugs available to physicians has been a continuing concern to me, many other Members of the Congress, to the FDA, to the medical community and others. The so-called "drug lag" and the need to expedite drug approvals has been widely studied and recommendations for improvements abound. Indeed, FDA is in the midst of revising its regulations and procedures for new drug approvals.

Astonishingly, then, the Committee has reported a bill which is likely to reduce FDA's ability to improve its new drug approval procedures and its timeliness in acting on new drug applications. FDA has expressed concern in its "Technical Comments" that the bill reported by the Committee will result in a "substantial increase in work load during the first few years immediately following enactment." It is obvious that this increase in workload will obligate FDA to reallocate personnel from new drug review to ANDA review. Because the bill also contains time limits on FDA's actions on ANDAs which are far more restrictive than those for NDAs,* this problem will be further exacerbated. It is apparently the Committee's view that review of ANDAs is a more important priority for FDA than NDAs. I take strong exception to that judgment.

As FDA has suggested, a phase-in of eligibility of ANDAs would ameliorate much of its workload burden while simultaneously making available immediately for ANDA treatment six of the drugs that are among the top selling prescription drug products. I urge the Members of the House to consider this idea among others as a way to greatly improve upon this bill.

C. Disclosure of proprietary data

The bill reported by the Committee provides for the public disclosure of all of the extensive and costly research data generated by research-oriented pharmaceutical companies, even though those safety and effectiveness data may be of significant value to foreign competitors or may retain proprietary value in the United States. These data may well retain commercial value, even when FDA no longer requires an applicant to submit them for approval of a drug (*i.e.*, when an ANDA may be filed with FDA, the full data are not needed). The data may still be valuable, for example, because in many foreign countries all or a portion of these data are needed to obtain approval. These data will be valuable particularly in those countries which do not recognize U.S. patents. By providing for the

*Under current law, the 180-day time period for acting on an NDA does not begin until the NDA is "filed," i.e., is nearly ready to be approved by FDA. Under H.R. 3605, the 180-day time period for acting on an ANDA begins when the ANDA is submitted. A substantial time may pass between "submission" and "filing" while the application is brought into conformity with FDA's criteria for approval.

release of these data, the bill hands to foreign competitors of U.S. drug firms, for the mere price of photocopying charges, data which cost many millions of dollars to obtain and which can be used to obtain approval to market drugs in competition with the owner and generator of the data. This provision of H.R. 3605 is hardly the way to protect and improve the competitiveness of America's pharmaceutical industry.

It should also be noted that this provision of H.R. 3605 has significant resource implications for FDA. Under the Freedom of Information Act, FDA is obligated to respond to requests for documents in its files, including the voluminous safety and effectiveness data made available by the bill, ordinarily within ten days. Since the enactment of the FOI Act, FDA has consistently received more requests for documents than virtually any other Federal agency. In 1983, FDA received over 39,000 FOI requests. One hundred twenty-five "full time equivalents," many highly trained scientists and doctors, were required to process these requests. Under H.R. 3605, over twenty years of safety and effectiveness data and information will, immediately upon enactment, be available for disclosure. If FDA were to receive requests for even a modest part of those data, the workload and resource burdens would be staggering. I fail to see how the public benefits by having FDA be forced to divert scarce technical personnel and resources to processing FDA requests and ANDAs, at the expense of new drug applications and other important public health functions.

II. TITLE II—PATENT TERM RESTORATION

H.R. 3605 contains many significant revisions to our patent laws. Rather than restoring patent terms lost during extensive regulatory review periods, these revisions eliminate many of the significant rights which currently accrue to the patent owner. Moreover, the patent term restoration provisions are so restrictive that their effect may well be largely illusory. Innovation is not encouraged by these patent provisions.

A. Loss of patent rights

I am advised that it has long been accepted that to use, sell or make a patented product during the life of the patent constitutes patent infringement. This aspect of the rights accruing to the patent owner was recently reaffirmed in the context of generic drugs in the so-called *Bolar* case. The United States Court of Appeals for the Federal Circuit held, consistent with prior law, that a generic drug company may not formulate and test its version of another company's patented drug until the patent term expires. The *Bolar* decision is sound law and should be retained.

H.R. 3605, however, would overrule *Bolar* and thereby permit a generic drug company to engage in acts which heretofore would have constituted patent infringement. It is extremely doubtful that it is sound policy in a bill designed to restore patent life, to dramatically cut back on existing patent rights.

I am also concerned that the constitutional implications of this provision of H.R. 3605 have not been considered. By overruling *Bolar*, the bill retrospectively deprives the patent holder of valua-

ble rights. Patent rights represent both a contractual right between the patent holder and the U.S. Government and a recognized property right. The Constitution prevents the Government from impairing the rights of contract and from "taking" or depriving one of a property right without just compensation. By overruling *Bolar* for patents already issued, H.R. 3605 violates these important protections found in our Constitution.

B. Restrictions on patent term restoration

Under H.R. 3605, most patents will not be eligible for restoration, even though they may cover products or methods of use, formulation or administration, of innovative drugs which required many years and great expense to research and develop and even though many years may have been devoted to securing an approval to market from the FDA. The bill thus fails to achieve one of its principal purposes: to ensure that sufficient incentives exist for innovation.

A few examples of the restrictive approach to patent term restoration will demonstrate the inadequacies of H.R. 3605.

Under present law, a patent can be obtained containing a broad claim (genus) covering many compounds. It is difficult and requires a large investment by the innovator, but is still possible subsequently to obtain a patent for specific claims (species) on a few specific compounds encompassed within the genus. Under the bill, should a patent holder obtain a patent with species claims covered by a previously-issued genus patent, the patent holder could not obtain restoration of the term of the species patent.

In addition, under present law, the Patent Office can require that the claims in a patent application be divided and prosecuted in separate patents. Under the bill, the first issued patent of the series would be the only patent term entitled to restoration, and subsequently issued patents of the series would be precluded from restoration. Accordingly, unless an FDA approved product is claimed within the first issued patent of the series, restoration of a patent term covering the product would not be available. During the patent application process, it is impossible to know which drug or drugs will ultimately be successfully tested and marketed. Therefore, a patent holder is being denied the benefit of patent term restoration due to circumstances beyond its control.

Another exception to patent term restoration encompassed by H.R. 3605 would occur where one patent covers two FDA approved drugs. Any claims in the patent covering the second FDA approved drug could not be restored. Accordingly, only one restoration is available per patent even though a company may have expended considerable resources in developing each FDA approved product.

The bill also limits availability of patent term restoration for method of manufacturing patents (not using DNA technology), including the limitation that no other type of patent has been or "may be issued for any known therapeutic purposes" claiming the method of using the product.

By excluding so many patents from eligibility for term restoration and by making the eligibility for restoration of some patents turn on circumstances beyond the control of the innovator, the bill falls well short of providing the incentives for innovation that it

purports to achieve. It is not necessary, of course, that every patent be eligible for extension in order for reasonable incentives to innovate to exist. Rather, the bill should provide for patent term restoration for all significant innovations, be they in discovering new chemical entities, new dosage forms, new uses or species of substances previously covered by broad genus patents. The restrictive eligibility provisions of H.R. 3605 make patent term restoration a haphazard and infrequent event. Innovation is not encouraged when the prospect of meaningful patent life is left to chance and happenstance and when most innovations covered by patents will not be eligible for term restoration.

H.R. 3605 also makes other significant changes to our patent laws which neither I nor this Committee have had time to learn about or consider.

III. CONCLUSION

It is distressing and regrettable that this Committee has reported a complex, lengthy and highly significant piece of legislation without holding hearings in either the Health Subcommittee or in the full Committee and after what can only be described as a pro forma markup. It is equally distressing that this Committee reported a controversial bill which changes significantly our patent laws, an area which escapes even the broad jurisdiction of this Committee.

I share with other Members the desire to restore patent life lost during periods of regulatory review and the desire to facilitate the approval of generic drugs. I object, however, to the precipitous and superficial consideration of the bill by the Committee and to its failure to provide for and consider, the views of all parties affected by the legislation.

THOMAS J. BLILEY, Jr.

HOUSE REPORT NO. 98-857, Part II

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The Committee on the Judiciary, to whom was referred the bill (H.R. 3605) to amend the Federal Food, Drug, and Cosmetic Act to authorize an abbreviated new drug application under section 505 of that Act for generic new drugs equivalent to approved new drugs, and for other purposes, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

* * * * *

BACKGROUND OF PATENT TERM LEGISLATION

For the last 113 years patent terms have been set at seventeen years. Beginning in the late 1970's, however, patent owners began to complain that the period of Federal government regulatory review eroded the effective market life of their patents. This view was first formally voiced by President Carter's Advisory Committee on Industrial Innovation.

During the 96th Congress an attempt was made to legislate in this area. Congressman Kastenmeier, chairman of the Subcommittee on Courts, Civil Liberties and the Administration of Justice, requested that an amendment to an unrelated patent bill by Mr. Sawyer be withdrawn in return for an agreement that the bill would be given full consideration during the next Congress. This request was agreed to.

During the 97th Congress the Subcommittee held extensive hearings on H.R. 1937.[1] The Subcommittee also commissioned a study of the issue by the Office of Technology Assessment.

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As a result of those hearings the Subcommittee marked up the bill and reported a clean bill, H.R. 6444. The Committee on the Judiciary approved H.R. 6444 on August 4, 1982.[2] The bill was brought up on the Suspension calendar in September 1982 but failed to achieve two-thirds by a narrow margin.

Also during the 97th Congress the Senate held hearings on patent term legislation.[3] The Senate passed S. 255 unanimously, but because of the failure of the House measure no public law ensued.

It should also be noted that during the 97th Congress opponents of patent term legislation, Congressmen Waxman and Gore, also held hearings on the subject.[4]

98th CONGRESS

Relatively early this Congress, Congressman Synar introduced H.R. 3502, a measure largely similar to the bill which had passed the Senate last Congress. In the Senate Senator Mathias introduced a companion bill, and has held hearings on the measure this Congress. The original Synar bill, H.R. 3502, had approximately one hundred co-sponsors, including leadership figures from both parties.

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[1] Patent Term Restoration Act of 1981: Hearings on H.R. 1937, H.R. 6444, and S. 255, Before the Subcommittee on Courts, Civil Liberties and the Administration of Justice of the House Comm. on the Judiciary, 97th Congress, 1st Session (1981).

[2] H.R. Rep. No. 696, 97th Congress, 2nd Session (1982); see also S. Rep. No. 138, 97th Congress, 1st Session (1981).

[3] Patent Term Restoration Act of 1981: Hearings on S. 255 Before the Senate Comm. on the Judiciary, 97th Congress, 1st Session (1981).

[4] Health and the Environment Miscellaneous—Part 7: Hearings on Childhood Immunizations; Cost Effectiveness of the Influenza Vaccine; Proposed Family Planning Regulation; Orphan Drug Act—H.R. 5238, Before the Subcommittee on Health and the Environment of the House Comm. on Energy and Commerce, 97th Congress 2d Session (1982); Pharmaceutical Innovation—Promises and Problems: Hearings on Breakthrough Drugs Before the Subcomm. on Natural Resources, Agriculture Research and Environment and the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology, 97th Congress, 1st Session (1981).

Also early this Congress, Congressman Waxman introduced H.R. 3605, a bill relating to the approval process for generic drugs. The original Waxman bill was a page and a half in length. This bill was the subject of a day of hearings in the Committee on Energy and Commerce, Subcommittee on Health and Environment. The Subcommittee then reported the bill without amendment. After the markup was concluded, Congressman Waxman engaged in extensive negotiations with interested parties. The primary participants were the Generic Pharmaceutical Industry Association (GPIA) and the Pharmaceutical Manufacturers Association (PMA). As a result of these discussions, when the bill was marked up in the Committee on Energy and Commerce Mr. Waxman offered an amendment in the nature of a substitute. The substitute was adopted and forms the basic text of H.R. 3605. House Report 98-857, Part I.

Background on FDA Approval Process

Since the passage of the Drug Amendments of 1962, the FDA has permitted the marketing of generic drugs under two different sets of rules. With respect to drugs approved before 1962 (i.e. those approved under a standard of safety but not efficacy), FDA has permitted generic substitution without a requirement that the generic substitute duplicate previously approved tests. However, with respect to drugs approved after 1962, the FDA has adopted the view that generics must virtually duplicate the same health and safety tests conducted by the original applicant for marketing approval.

The FDA rules on generic drug approval for drugs approved after 1962 have had serious anti-competitive effects. The net result of these rules has been the practical extension of the monopoly position of the patent holder beyond the expiration of the patent. This is so because of the inability of generics to obtain approval for these post-1962 drugs without enormous expenditures of money for duplicative tests.

The first serious attempts at rectifying the inequities of this drug approval process were undertaken in the 95th Congress. The Carter Administration, under the leadership of Secretary Califano of the Department of Health and Human Services, and Dr. Kennedy of the FDA, proposed sweeping changes in the drug approval process.[5] Secretary Califano urged Congress to act for three reasons: (1) the exclusion of generics was anti-competitive; (2) the requirements of duplicative tests on humans unnecessarily endangered human health; and (3) the approval process diluted the resources of the FDA.[6] During the 96th Congress additional hearings were held [7] and the Senate eventually adopted a bill which opened up the FDA

[5] The Administration bill was introduced, after extensive consultation as H.R. 11611, and S. 2755.

[6] "Drug Regulation Reform Act of 1978," Hearing before the Subcommittee on Health and the Environment, Committee on Interstate and Foreign Commerce, United States House of Representatives, 95th Congress, 2d Session (1978); "Drug Regulation Reform Act of 1978," Hearings before the Subcommittee on Health and Scientific Research, Committee on Human Resources, United States Senate, 95th Congress, 2d Session (1978).

[7] "Drug Regulation Reform Act of 1979," Hearings before the Subcommittee on Health and Scientific Research, Committee on Labor and Human Resources, United States Senate, 96th Congress, 1st Session (1979).

drug approval process.[8] This comprehensive reform bill failed in the House for unrelated reasons.

SUMMARY OF H.R. 3605

H.R. 3605 contains two titles. The first title of the bill creates a new system for the approval of generic drugs by the Food and Drug Administration. This approval process for drugs approved by the FDA after 1962 has been severely criticized as too cumbersome and expensive. In essence the provisions of title I of H.R. 3605 extend the procedures for approval of generics for pre-1962 drugs to the later class of drugs.

Thus, under H.R. 3605 a general manufacturer may submit to FDA a request for approval of a generic substitute for any post-1962 drug. The generic manufacturer must establish that the proposed substitute is the same or therapeutically equivalent to the drug which has already been approved.

Under the approval process in H.R. 3605, a generic manufacturer may submit an application for approval to FDA before the so-called pioneer drug goes off patent. The generic may submit data establishing bioequivalency during this time period. In order to complete this application the generic manufacturer must conduct certain drug tests. In order to facilitate this type of testing, section 202 of the bill creates general exception to the rules of patent infringement. Thus, a generic manufacturer may obtain a supply of a patented drug product during the life of the patent and conduct tests using that product if the purpose of those tests is to submit an application to FDA for approval.

H.R. 3605 permits generic applications to be effective after a patent expires. In addition, H.R. 3605 provides that a generic manufacturer may request FDA approval to begin marketing before the patent on the drug has expired. Under current law, this situation is not an issue because of the cumbersome approval process. If the generic manufacturer seeks such an approval it must allege that the existing patent is invalid or will not be infringed. In this instance notification must be given by the generic to the patent holder concerning the application for FDA approval. In these cases the FDA may not approve the generic application until either: (1) 18 months have expired or (2) a court has determined that no infringement will take place. After the expiration of 18 months, if there has been no intervening judicial determination, the FDA will approve the generic application, even if the drug is still on patent.

Finally, title I also provides for a four year grant of market exclusivity to be granted by the Commissioner of the FDA for unpatentable substances which have been approved for use as drugs by the FDA.

TITLE II

This title of the bill addresses the question of patent term extension. As noted above, proponents of this type of legislation have argued that the reduction of the effective market life of a patent

[8] S. Rept. 96-331, 96th Congress, 1st Session 42-44, 50-51 (1979); 125 Congressional Record 22844-22875 (Sept. 25, 1979).

[page 6]

because of Federal regulatory review should be restored through an extension of the patent term. Alternatively, or additionally, some proponents of this approach have argued that without some form of legislative relief in this area there would be a diminished stimulus to innovation and research. Thus, it is argued that patent term extensions will create incentives for increased research expenditures.

The patent term extension provisions of the bill are relatively complex, and differ in many respects from the bill approved by the Committee on the Judiciary last Congress. In general, the bill provides that a patent may be extended for a period of up to five years if the patented drug (or other item subject to regulatory review by the FDA) has undergone regulatory review. The bill provides several general rules for calculating the period of the extension. First, only one-half of the testing phase may be counted. Second, a year-for-year matching extension is available for any time in the drug approval process that the drug spends awaiting a decision by the FDA. The five year rule is available to all drugs which have not yet undergone testing by the FDA. With respect to drugs which have been patented and tested but not yet approved by the FDA, the maximum period of extension is two years.

In addition to the five year rule listed above, the bill places an additional cap on the possible extension. In no case may the period of patent extension, when added to the patent life left after approval of the product, exceed fourteen years. Finally, any part or all of the patent extension may be cancelled if the applicant for an extension failed to act with due diligence in conducting tests or in the submission of data to the FDA.

As noted above, the other feature of the drug patent part of the bill is to statutorily modify the rules with respect to patent infringement.

HISTORY OF THE BILL IN THE COMMITTEE ON THE JUDICIARY

On June 21, 1984, H.R. 3605 was sequentially referred to the Committee on the Judiciary for a period not to extend beyond the 1st of August, 1984. The bill was referred to the Subcommittee on Courts, Civil Liberties and the Administration of Justice which held one day of hearings on the bill on June 27, 1984. Formal presentations at that hearing were made by:

Honorable Gerald J. Mossinghoff, Assistant Secretary and Commissioner of Patents and Trademarks; a panel including Robert J. Lewis, representing the Pharmaceutical Manufacturing Association and William Haddad, representing the Generic Pharmaceutical Industry Association; a panel consisting of John Stafford, President, American Home Products; Norman Dorsen, Professor of Law, New York University School of Law and William E. Schuyler, Jr., Esq. and Dr. Ronald E. Cape, Chairman, Cetus Corporation, Emeryville, California.

In addition, written statements suggesting amendments to the legislation have been received from Congressmen Mica and Coughlin. Written comments favoring the bill have also been received from the following labor organizations: the American Federation of Labor and Congress of Industrial Organizations (AFL-CIO); International Union, United Automobile, Aerospace and Agricultural

Implement Workers of America (UAW); American Federation of State, County and Municipal Employees (AFSCME). Further statements in support of the bill have been received from the American Association of Retired Persons (AARP); Consumer Federation of America (CFA); National Council on Senior Citizens (NCSC). Additional comments have also been received by the American Society of Hospital Pharmacists in support of the bill.

Statements in opposition to parts of the bill have been received from the American Intellectual Property Law Association (AIPLA) and the Patent, Trademark and Copyright Section of the Bar Association of the District of Columbia.

SUMMARY OF HEARING

The proponents of the legislation urged its adoption as the best possible compromise between two competing economic interests. The Commissioner of Patents and Trademarks objected to the legislation on several grounds. Commissioner Mossinghoff urged the Committee to adopt the patent term procedures and rules contained in the Committee reported bill from last Congress and to reject the proposed changes in the law of patent infringement. Dr. Ronald Cape of CETUS Corporation urged expanded protection from the abbreviated new drug application process for biotechnology which uses recombinant DNA.

Finally, a group of drug companies opposed to the legislation in its current form articulated its reservations. They argue that the bill will hamper innovation and research, create unnecessary litigation and unconstitutionally take property from patent owners.

Committee on the Judiciary Deliberations

The Committee considered six amendments. Two amendments were adopted, and four amendments were rejected.

The first amendment adopted was first approved by the Subcommittee on Courts, Civil Liberties and the Administration of Justice and relates to animal drugs. This amendment deleted authority for patent term extension for animal drugs, because these substances were dealt with in another bill before the Committee, H.R. 6034.

The second amendment approved by the Committee was offered by Mr. Kastenmeier. This amendment deleted from the bill authority of the Commissioner of the Food and Drug Administration to grant exclusive marketing authority for unpatentable substances. The Committee concluded that such authority to issue second class "patents" should not be granted without a strong showing of need. There was no such showing. Further, the Committee concluded that authority to grant the equivalent of a monopoly is something which should be limited to appropriate Federal agencies such as the Patent and Trademark Office in the case of non-obvious, useful inventions.

The first amendment rejected by the Committee was offered by Mr. Hughes. The Hughes amendment would have permitted the granting of a patent term extension for the substances regulated by the bill for each regulatory review period. The net result of the amendment was to permit multiple patent term extensions on what was essentially the same drug product. This amendment was

supported by the Patent and Trademark Office (PTO). The PTO argued that the version of H.R. 3605 reported by the Committee on Energy and Commerce would create two different types of patents for drugs; those which are extendable and those which are not extendable. The latter category, they claim, includes subsequent use, method and composition patents.

The Committee considered these arguments and rejected them for two reasons. First, the Committee accepted the rationale put forward by the Committee on Energy and Commerce concerning the need to avoid multiple patent term extensions. Our sister Committee argued that the only patented product which experiences any substantial regulatory delay is the first product patent (or if there is no product patent, the first process patent). Therefore, they reason that subsequent patents on approved drug products are frequently not the same magnitude of innovation as occurs with respect to the initial patent. Thus, the Committee on Energy and Commerce concluded on public policy and health policy grounds that only the first patent on a drug-type product should be extended.

The second amendment rejected by the Committee was offered by Mr. Moorhead. This amendment would have permitted generic drug manufacturers to conduct FDA related tests during the life of a patent, but only during the last year of any period of patent term extension. The net effect of this amendment would have been to delay the opportunity of doing such testing for nearly two decades.[9] Mr. Moorhead argued that section 202 of the bill constituted an unconstitutional taking of property without just compensation in violation of the Fifth Amendment to the Constitution. The Committee rejected this argument for reasons set forth in greater detail in the section by section analysis. See page 26, infra. Mr. Moorhead also argued that it was unfair for persons holding existing patents to be forced to give up certain property rights during the life of that patent. He asserted that this amendment would permit such testing but only as a condition for obtaining a patent term extension.

The Committee rejected the Moorhead amendment for two reasons. First, the only activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute. The patent holder retains the right to exclude others from the major commercial marketplace during the life of the patent. Thus, the nature of the interference with the rights of the patent holder is not substantial. Second, the Committee accepted the public policy rationale of our sister Committee on Energy and Commerce. They reasoned that without section 202 generic manufacturers would be required to engage in these bioequivalency tests after the expiration of the patent.[10] This would result in delays of about two years after the expiration of the patent before a generic could go on the market. Thus, the Committee on Energy and Commerce reasoned that sec-

[9] This is so became for the most part the bill is prospective as to patent extensions. So for a patent granted in 1985 with a 5-year extension the testing would not occur until 2006 (1985+17+5−1 year).

[10] Alternatively these tests could be conducted outside the United States in a country where the pioneer drug company does not have patent protection.

tion 202 of the bill was essential to implement the policy objective of getting safe and effective generic substitutes on the market as quickly as possible after the expiration of the patent.

The third amendment rejected by the Committee was offered by Mr. Sawyer. This amendment would have changed the trigger which set in motion the commencement of patent validity litigation. Mr. Sawyer argued that the time period when the bill's litigation procedures come into play should occur later than is provided in the bill. The Committee rejected the amendment because the Committee reported bill provides that the initial submission by the generic manufacturer must be substantially complete (including the results of any required bioequivalency tests). See House Report 98-857, Part I, 24-25. Thus, the Committee concluded that requiring the patent litigation to await the formal acceptance of the data by the FDA would only serve to unnecessarily protract the resolution of that litigation.

The fourth amendment rejected by the Committee was also offered by Mr. Sawyer. This amendment would have required that the FDA may not approve a generic substitute for marketing during the life of a valid patent. Mr. Sawyer's amendment would have required that either the patent expire before approval, or that there be a final decision by a Federal District Court that the patent in question was not valid. The Committee rejected the amendment for several reasons. First, the Committee recognized that under current law the FDA has statutory and regulatory authority to approve of generic substitutes in three instances.[11] Under this existing authority the FDA does not examine or question the patent status of the previously approved drug.[12]

Also under current law, if the generic obtains approval and goes on the market before the patent expires, then the patent holder can sue for patent infringement. Thus, under current Federal law the FDA does not assist the patent holder in enforcing a patent.

The provisions of the bill reported by the Committee on Energy and Commerce modify this rule by providing that if a generic files for approval and requested marketing authority during the life of the patent that the FDA cannot act immediately. Under the bill the generic must notify the FDA that they are claiming that the patent is invalid.[13] The generic must also notify the patent holder. The patent holder must then commence litigation within 45 days to assert the validity of the patent. Once that litigation has commenced the FDA cannot grant approval until the earlier of two events occurs: (1) either the expiration of 18 months; or (2) a court decision finding the patent invalid. This provision was added by the Committee on Energy and Commerce to accommodate the competing concerns of the PMA and the generic manufacturers. The PMA

[11] FDA currently has authority to approve generic substitutes for pre-1962 drugs, antibiotics and a narrow class of post-1962 drugs where sufficient medical literature exists. See 21 U.S.C. 355(b); 43 Fed. Reg. 39127 (Sept. 1978) (relating to pre-1962 drugs); 21 U.S.C. 357 (a) and (b) (relating to antibiotics); 46 Fed. Reg. 27396 (May 19, 1981) (relating to post-1962 paper ANDA approvals); *see also* section 3(c)(1)(D)(i)-(iii) (relating to approval of generic pesticide substitutes by EPA whithout relation to patent status).

[12] "The patent laws do not have any bearing on the enforcement of the Federal Food, Drug and Cosmetic Act . . . FDA reviews application(s) without considering any patent issue." 45 Fed. Reg. 72598 (Oct. 31, 1980) (statement by FDA).

[13] Alternatively, the generic could claim that its application would not infringe an existing patent. This notification is likely to produce the same type of patent litigation.

was willing to compromise on the provisions of title I of the bill (relating to abbreviated new drug application procedures (ANDAs)) in exchange for some greater protection of existing human pharmaceutical patents. The generic manufacturers, on the other hand, were willing to live with an eighteen-month rule because of other provisions of the bill.

In light of the foregoing, the net effect of the Sawyer amendment would have been to substantially delay generics from getting onto the market when they seek to challenge the validity of a patent. According to the statistics of the Judicial Conference of the United States, the median time between filing and disposition of a patent suit is 36 months. Annual Report of the Director of the Administrative Office of the United States Courts—1982, at 253. Over ten percent of these cases take more than 77 months. Thus, a requirement that FDA defer generic approval until after a court decision of patent invalidity would substantially delay FDA approvals. Of course, in the event that the FDA approves a generic because of the expiration of 18 months without a court decision, and it is later determined that the patent is valid, the patent owner may still recover damages from the generic.[14] Therefore, in most cases the bill affords greater protection for patent holders than current law.

SECTIONAL ANALYSIS OF "DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984"

GENERAL

The Federal Food, Drug, and Cosmetic Act (hereinafter FDCA), 21 U.S.C. 355, establishes a system of premarketing clearance for drugs. Generally, the FDCA prohibits the introduction into commerce of any new drug unless a new drug application (NDA) filed with the Food and Drug Administration (FDA) is effective with respect to that drug. 21 U.S.C. 335(a). The FDA is part of the Department of Health and Human Services (HHS) and the Secretary of HHS has delegated her responsibilities under the Act to the Commissioner of Food and Drugs. 21 U.S.C. 21 CFR 5.10. A new drug is one not generally recognized by qualified experts as safe and effective for its intended use. 21 U.S.C. 321(p)(1). The Government can sue to enjoin violations, prosecute criminally, and seize and condemn articles. 21 U.S.C. 331(d), 332(a), 333 and 334.

The FDCA establishes an introduction procedure for new drugs, designed to elicit sufficient scientific information about a drug, including reports on investigations, composition, methods and precautions in manufacture, and samples of the drug, which will permit an intelligent assessment of its safety and efficacy. 21 U.S.C. 355(b).

The law provides standards under which, after notice and hearing, the FDA can refuse to allow a NDA to become effective, 21 U.S.C. 355 (c) and (d), or can withdraw a NDA in effect on the basis of new evidence that the drug was unsafe. 21 U.S.C. 355(e). Generally, the FDA must approve or disapprove an application within 180 days. The FDA is directed to refuse approval of NDA and to withdraw any prior approval of NDA if "substantial evidence" that

[14] See proposed section 271(e)(4) and 35 U.S.C. 271.

the drug is effective for its intended use is lacking. 21 U.S.C. 355 (d) and (e). Substantial evidence is defined to include "evidence consisting of adequate clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof." 21 U.S.C. 355(d).

FDA orders refusing or withdrawing a NDA are reviewable in the court of appeals. 21 U.S.C. 355(h). Other kinds of FDA orders may be reviewed in federal district courts under the Administrative Procedure Act (APA).

The Act provides an alternative procedure for drugs intended solely for investigational use. 21 U.S.C. 355(i). Compliance with a comprehensive set of FDA regulations is required. 21 CFR 312.1 et seq.

Finally, section 355(j) requires records and reports relating to clinical experience and other data or information regarding an approved drug to be made available to the FDA which shall handle them with due regard for the professional ethics of the medical profession and the interests of patients.

SUMMARY OF THE BILL

The "Drug Price Competition and Patent Term Restoration Act of 1984" (H.R. 3605) consists of two titles which affect introduction procedures and patent requirements for certain kinds of generic new drugs. Title I of the bill allows drug manufacturers to use an abbreviated new drug application (ANDA) when seeking approval to make generic copies of drugs that were approved by the FDA after 1962. Title II of the bill encourages drug manufacturers to assume the increased costs of research and development of certain products which are subject to premarketing clearance by restoring some of the time lost on patent life while the product is awaiting FDA approval.

Section 1 of the bill sets out the short title: "Drug Price Competition and Patent Term Restoration Act of 1984".

Title I—Abbreviated New Drug Applications

Section 101 amends section 505 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355, to graft on the NDA procedure previously described, authority for an abbreviated new drug application (ANDA) procedure applicable to drug manufacturers seeking approval to make generic copies of drugs that were approved by the FDA after 1962. There are "[a]n estimated 150 drug products approved after 1962 [that] are currently off patent and would become available for generic copy using the ANDA procedure proposed in this bill." H. Rept. 98-857, Part I, at 19.

The new ANDA procedure is set forth in subsection (j) of the introductory procedure provisions of current law. 21 U.S.C. 355. As a consequence, existing subsection (j), relating to records and reports which have to be made available to the FDA by manufacturers of approved drugs, is redesignated subsection (k).

Paragraph (1) of proposed subsection (j) authorizes any person to file an ANDA.

Paragraph (2)(A) of proposed subsection (j) describes the information which has to be included in the ANDA. Specifically, the ANDA must include:

(i) sufficient information to show that the conditions of use prescribed, recommended or suggested in the proposed labeling for which the applicant is seeking approval are the same as those that have been previously approved for the listed drug;

(ii)(I) if that listed drug, referred to in clause (i), has only one active ingredient, sufficient information to show that the active ingredient of the generic is the same as that of the listed drug, or

(ii)(II) if the listed drug, referred to in clause (i), has more than one active ingredient, sufficient information to show that all of the active ingredients in the generic drug are the same as those of the listed drug, or

(ii)(III) if that listed drug, referred to in clause (i), has more than one active ingredient, and if one of the active ingredients in the generic drug is different and the applicant is seeking approval under paragraph (2)(C), relating to ANDAs for drugs which are different, sufficient information to show that the other active ingredients of the generic are the same as the active ingredients of the listed drug as well as sufficient information to show that the different active ingredient is an active ingredient or a listed drug or of a drug that is not a new drug as defined by section 201(p) of the Act, 21 U.S.C. 321(p), and such other information about the different active ingredient that the ANDA may require.

(iii) sufficient information to show that the route of administration, the dosage form and the strength of the generic drug are the same as those of the listed drug, or if the generic departs from the listed drug in any one of these particulars, such information regarding that difference as the FDA may require;

(iv) sufficient information to show that the generic drug is bioequivalent [15] to the listed drug, except that if the applicant is seeking approval under paragraph (2)(C), relating to ANDAs for drugs which are different, sufficient information to show that the active ingredients of the generic are of the same pharmacological or therapeutic class as those of the listed drug and can be expected to have the same therapeutic effect when administered to patients for an approved condition for use;

(v) sufficient information to show that the proposed labeling for the generic drug is the same as that of the listed drug except for approved changes when approval has been obtained under paragraph (2)(C), relating to ANDAs for drugs which are different, or because the generic and the listed drug are produced or distributed by different manufacturers;

(vi) the scientific information about a generic that is required for a NDA under existing law, 21 U.S.C. 355(b)(2)-(5), as redesignated by section 103(a) of this bill (§ 355(b)(1)(B)-(F)), namely a full list of its component articles and composition, a

[15] The term bioequivalent is defined in section 101 of the bill.

full description of methods and precautions in manufacture, drug and component article samples, and a specimen of the proposed label;

(vii) a certification by the applicant (in the opinion of the applicant and to the best of such applicant's knowledge) of patent information applicable to the listed drug if that information has been submitted under subsections (b) and (c) of existing law as proposed to be amended by section 102(a)(1) and (a)(2) of the bill, infra. With respect to all product patents which claim the listed drug and all use patents which claim an indication for the drug for which the applicant is seeking approval, i.e., a controlling use patent, the applicant must certify, in the opinion of the applicant and to the best of the applicant's knowledge—

(I) that the patent information as required under subsections (b) and (c) of existing law as proposed to be amended by section 102; (a)(1) and (a)(2) of the bill, infra, has not been filed;

(II) that one or more of the product or controlling use patents as hereafter required to be provided for NDAs have expired;

(III) that one or more of the product or controlling use patents as hereafter required to be provided for NDAs will expire on a specified future data, and

(IV) that one or more of the product or controlling use patents as hereafter required to be provided for NDAs either are invalid or will not be infringed.

(viii) a statement when appropriate that an applicant is seeking approval for an indication not previously claimed by any use patent.

The FDA cannot require that an ANDA contain information above and beyond that required by clauses (i) through (viii), supra.

Paragraph (2)(B) of proposed subsection (j) requires additional patent information to be included in the ANDAs of applicants who certify pursuant to subparagraph (A)(vii)(IV), supra, that one or more of the product or controlling use patents either are invalid or will not be infringed. Proposed subparagraph (B)(i) provides that the ANDA in these circumstances shall state that the notice required by clause (ii) of this subparagraph has been given to the affected owner(s) of a patent which is subject to the certification requirement or their representatives and to the affected holder of an approved NDA which contains the patent information required by introduction procedures of existing law as amended by section 102(a)(1) and (a)(2) of the bill.

Clause (ii) provides that the required notice shall state that an ANDA which contains data from bioavailablity or bioequivalence studies has been submitted along with a certification seeking approval for marketing a drug covered by an unexpired patent. Additionally, the notice shall explain in detail the legal and factual basis of the applicant's opinion that the relevant patent is invalid or will not be infringed.

Subparagraph (iii) requires that in the case of an ANDA which is subsequently amended so as to bring it within this notice require-

ment, notice shall be given when the amended application is submitted.

Paragraph (2)(C) of proposed subsection (j) relates to ANDAs for drugs which are different from the listed drugs. Generally, a person would be prohibited from submitting an ANDA in these circumstances unless the variance is one permitted by the law as amended by this bill and the FDA has granted a petition requesting the change. If an applicant wishes to vary one active ingredient or the route of administration, dosage form or strength of the generic drug from the listed drug, it must petition the FDA for permission to file an ANDA for the differing generic drug. The FDA has 90 days to approve or disapprove the petition from the date of its submission. The FDA shall approve a petition to submit an ANDA for a differing generic drug unless clincial studies are needed to show the safety and effectiveness of the change.

Paragraph (3) of proposed subsection (j) requires the FDA to approve an ANDA unless it finds one of the following:

(A) that the methods used in, or the facilities and controls used for, the manufacture, processing and packing of the generic drug are inadequate to assure and preserve its identity, strength, quality and purity;

(B) that the ANDA does not contain sufficient information to show that each of the conditions for use for the generic drug have been previously approved for the listed drug;

(C)(i) that the active ingredient of the generic drug is not the same as that of the listed drug and the listed drug has only one active ingredient,

(C)(ii) that the active ingredients of the generic drug are not the same as those of the listed drug and the listed drug has more than one active ingredient, or

(C)(iii) that the active ingredients of the generic drug differ from those of the listed drug and a petition permitting a change in one active ingredient has been granted but the other active ingredients of the generic drug are not the same as those of the listed drug or the different active ingredient in the generic is not a listed drug or if the different active ingredient is a new drug as defined by section 201(p) of the Act, 21 U.S.C. 321(p);

(D)(i) that an ANDA does not show that the route of administration, dosage form, or strength of the generic drug are all the same as those of the listed drug, or

(D)(ii) that an ANDA for a generic drug which has a different route of administration, dosage form, or strength from the listed drug but the petition regarding the change has not been approved under paragraph (2)(C);

(E) that an ANDA does not contain all of the information that the FDA required in previously granting a petition allowing for a difference in the generic drug from the listed drug;

(F) that an ANDA for a generic drug whose active ingredients are the same as those of the listed drug does not show that the generic drug is bioequivalent to the listed drug or, if a petition regarding a change in one of the active ingredients in a combination generic has been granted, that the ANDA does not show that the active ingredients of the generic drug are of

the same pharmacological or therapeutic class as those of the listed drug or does not show that the differing generic combination drug can be expected to have the same therapeutic effect as the listed combination product when administered to patients for an approved condition of use;

(G) that the ANDA does not show that the proposed labeling for the generic drug is the same as that of the listed drug (except for changes in the proposed labeling of the generic drug because a petition regarding a change has been granted and changes from a switch in producer or distributor);

(H) that on the basis of intrinsic or extrinsic information the inactive ingredients of the generic drug are unsafe for use under the conditions prescribed, recommended, or suggested in the proposed labeling for the generic drug or because the composition of the generic drug is unsafe under approved conditions of use;

(I) that approval of the listed drug has been withdrawn or suspended for reasons of safety or effectiveness;

(J) that an ANDA does not meet any of the requirements set forth in paragraph (2)(A), relating to ANDA's for drugs which are the same;

(K) that an ANDA contains any untrue statement of material fact.

Paragraph (4)(A) of proposed subsection (j) requires the FDA to approve or disapprove an ANDA within 180 days of the initial receipt of the application. By mutual agreement of the FDA and the applicant, that period may be extended.

Paragraph (4)(B) of proposed subsection (j) allows an ANDA approval to become effective according to relevant patent-related circumstances. Thus, under clause (i) if an applicant certifies in an ANDA that patent information has not been supplied with respect to a NDA as hereafter is required or that the relevant patents have expired, approval of the ANDA would become immediately effective. Under clause (ii), if the applicant on the basis of supplied information certifies that the patent or patents will expire on a specified future date, approval of the ANDA becomes effective on that date.

Clause (iii) would authorize a flexible schedule of ANDA approval-effectiveness dates when the applicant certifies that one or more of the product or controlling use patents are invalid or not infringed. Generally, approval of the ANDA in these circumstances could become effective after a 45-day hiatus. An approval of an ANDA would not become effective in these circumstances, however, if within 45 days of the receipt of notice of the certification an action is brought for patent infringement regarding one or more of the patents subject to that certification. In that event, approval of the ANDA could not be effective until 18 months after the notice of the certification was provided or until a court decision issues, if before the expiration of the 18 month time period a court decides such patent is invalid or not infringed the approval shall be made effective on the date of the courts order. If the court decides such patent has been infringed under 35 U.S.C. 271(e) the approval shall be made effective on the date the court orders.

Each party to a patent infringement suit is charged to reasonably cooperate in expediting the action. Failure by either party to cooperate in a reasonable manner may be used by the court to reduce or lengthen the time, as appropriate, before an ANDA approval becomes effective. No action for a declaratory judgment regarding patent infringement can be brought within the 45 days allowed for notice of certification of patent invalidity or non-infringement. An action for a declaratory judgment regarding infringement of a patent shall be brought in the judicial district where the defendant has its principal place of business or a regular or established place of business.

If an ANDA certifying patent invalidity or non-infringement is filed subsequent to an ANDA for the same listed drug that has made a similar certification, clause (iv) provides that the approval of the subsequent ANDA can be made effective sooner than 180 days after the previous applicant has begun commercial marketing, or the date on which the court rules the patent invalid or not infringed, whichever occurs first.

Paragraph (4)(C) of proposed subsection (j) provides that in the event of FDA disapproval of an ANDA, the agency shall give the applicant notice of the opportunity for a hearing on the issue of the approvability of the ANDA. In order to obtain a hearing, the applicant shall request it in writing within 30 days of the notice. The hearing may begin not later than 120 days after the notice. However, a later date may be set by mutual agreement. The hearing shall be conducted as expeditiously as possible. The FDA's decisional order shall be issued within 90 days after the date for filing final briefs.

Paragraph (4)(D) of proposed subsection (j) provides for an interim rule regarding ANDA approval effectiveness in the case of certain generic drugs whose listed drugs were originally approved between January 1, 1982 and the date of enactment of this bill. The clause provides that during this transitional period the FDA may not make effective the approval of an ANDA for a drug which includes an active ingredient (including any ester or salt of the active ingredient) until 10 years after the date of approval of the NDA.

Paragraph (5) of proposed subsection (j) relates to the consequences on an approved ANDA worked by withdrawal or suspension of approval of the listed drug. The approval of an ANDA shall be withdrawn or suspended for safety or effectiveness reasons as provided in section 505(e)(1)-(4) of the Act, 21 U.S.C. 355(e)(1)-(4). Similarly, the approval of an ANDA will also be withdrawn or suspended if it refers to a drug whose approval is withdrawn or suspended under this paragraph. Finally, the approval of an ANDA shall be withdrawn or suspended if the FDA determines that the listed drug has been voluntarily withdrawn from sale due to reasons of safety or effectiveness.

The ANDA must be withdrawn or suspended from sale for the same period as the approval of the drug to which it refers has been withdrawn or suspended. When the listed drug has been voluntarily withdrawn from the market and the FDA has determined that the listed drug was withdrawn due to safety or effectiveness reasons, the approval of the ANDA likewise must be withdrawn until

such time as the FDA determines that the listed drug was not withdrawn from sale for safety or effectiveness reasons.

Paragraph (6)(A), of proposed subsection (j) authorizes a program whereby information about listed drugs which could be copied would become available. Within 60 days after enactment of this bill, the FDA is required to publish and make available a list of drugs eligible for consideration in an ANDA. The list must include in alphabetical order the official and proprietary name of each drug which has been approved for safety and effectiveness prior to the date of enactment of this bill. If the drug was approved after 1981, the list must include the date of its approval and its NDA number. The list must specify whether in vitro or in vivo bioequivalence studies, or both, are required for ANDAs. Clause (i).

At 30-day intervals thereafter, the FDA must update the list to include drugs that have been approved for safety and effectiveness after enactment of this bill and drugs approved in ANDAs under this subsection. Clause (ii).

The FDA must include in the list patent information on listed new drugs required under section 102(a)(1) and (2) of this bill as that information becomes available. Clause (iii).

Paragraph 6(B) of proposed subsection (j) provides that a drug approved for safety and effectiveness under section 505(c) of the Act, 21 U.S.C. § 355(c) or under subsection (j) if this bill is enacted, shall be considered as published and thus eligible for approval in an ANDA on the date of its approval or the date of enactment, whichever is later.

Paragraph (6)(C) of proposed subsection (j) provides that a drug may not be listed as eligible for consideration in an ANDA if the approval of the former or pioneer drug is withdrawn or suspended for safety or effectiveness reasons under section 505(e)(1)-(4) of the Act, 21 U.S.C. § 355(e)(1)-(4), or if approval of the generic drug was withdrawn or suspended under paragraph (j)(5), supra, as authorized by this bill. Also, a drug may not be listed if the FDA determines that it has been voluntarily withdrawn for reasons of safety or effectiveness. In the event such a drug has already been listed, it must be immediately removed from the list.

A drug may not be listed so long as its approval is withdrawn or suspended. If the drug has been voluntarily withdrawn from market, it may not be listed until the FDA determines that the drug was not withdrawn from sale for safety or effectiveness reasons. A notice removing any drug from the FDA list regarding availability for copy shall be published in the Federal Register.

Paragraph (7) of proposed subsection (j) spells out the term "bioavailability" and the significance of bioequivalence for purposes of subsection (j) as authorized by the bill. The term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

A drug is to be considered bioequivalent to a listed drug if the rate and extent of absorption of the generic drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single or multiple doses. Clause (1). A generic drug may also be

considered to be bioequivalent to a listed drug if the extent of absorption of the generic drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the generic drug is intentional, is reflected in the proposed labeling, is not essential to the attainment of effective body drug concentration on chronic use, and is considered medically insignificant for the drug.

Section 102(a)(1) of the bill amends section 505(b) of the Act, 21 U.S.C. 355(b), to require certain patent related information to be filed with all new drug applications (NDAs) and with all NDAs previously filed but not yet approved. The FDA is required to publish the patent information upon approval of the NDA.

Section 102(a)(2) of the bill amends section 505(c) of the Act, 21 U.S.C. 355(c), to require that any previously approved NDA be amended within 30 days of enactment of this bill to include certain patent related information. The FDA is required to publish the patent information upon its submission. In order to accommodate these provisions, the current text of section 505(c) of the Act, 21 U.S.C. 355(c), is designated paragraph (1) and the new patent related provisions authorized by this bill would be designated paragraph (2)(A) and (B).

The patent information required includes the patent number and the expiration date of any patent which claims the drug in the NDA or which claims a method of using such drug with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engages in the manufacture, sale or use of the drug. When a patent is issued after the filing of a NDA, but before its approval by the FDA, the application would have to be amended to include the patent number and expiration date.

Section 102(a)(3)(A) of the bill amends section 505(d) of the Act, 21 U.S.C. 355(d), to provide that pending and future NDAs may not be approved unless they contain the described patent information. Appropriate redesignations of clauses of subsection (d) are authorized to accommodate this change.

Section 102(a)(3)(B) of the bill amends section 505(e) of the Act, 21 U.S.C. 355(e), to provide that a NDA may be revoked if the patent information is not filed within 30 days after receipt of a written notice from the FDA specifying the failure to provide that information.

Section 102(b)(1)–(6) of the bill amends provisions of existing law, as appropriate, in order to reconcile internal references to substantive and sectional changes that are proposed by the bill.

Section 103(a) of the bill amends section 505(b) of the Act, 21 U.S.C. 355(b), relating to the filing of a NDA, to redesignate subsection (b) as subsection (b)(1), and clauses therein presently numbered (1) through (6), as clause (A) through (F). Substantively, the changes proposed by section 103 of the bill require an applicant filing a Paper NDA for a listed drug under subsection (j)(6) of the bill, relating to drugs that may be considered for generic treatment, to make the same certifications regarding patents as apply

to the filing of an ANDA under subsection (j) of this bill. The FDA is required to make approval of Paper NDAs under the same conditions that apply to ANDAs submitted under proposed subsection (j). Finally, section 103 would apply the 10 year transition rule and the 4 year unpatentable substances rule to Paper NDAs.

Paper NDAs are defined as any application submitted under section 505(b) of the Act, 21 U.S.C. 355(b), in which the investigations relied upon by the applicant to show safety and effectiveness were not conducted by or for the applicant and the applicant has not obtained a right of reference or use from the person who conducted the investigations or for whom the investigations were conducted. Proposed paragraph (2).

Under subparagraph (2)(A), a Paper NDA which is submitted for a listed drug under subsection (j)(6) would have to include a certification by the applicant regarding the status of certain patents applicable to the listed drug if such information has been provided to the FDA. With respect to all product patents which claim the listed drug and all use patents which claim an indication for the drug for which the applicant is seeking approval (i.e., controlling use patent), the applicant must certify, as to one of four circumstances.

First, the applicant may certify that the patent information required under section 505 (b) and (c) of the Act, 21 U.S.C. 355 (b) and (c), as amended by this bill, has not been submitted if that is the case. Second, if appropriate, the applicant may certify that one or more of the product or controlling use patents provided have expired. Third, the applicant may certify when appropriate that one or more of the product or controlling use patents will expire at some specified future date. Finally, an applicant may certify on the basis of non FDA—supplied information that one or more of the product or controlling use patents are invalid or will not be infringed. Proposed subparagraph (2)(A)(i)–(iv).

When applicable, a Paper NDA for a listed drug must also state that the applicant is not seeking approval for an indication which is claimed by any use patent for which it has not made a certification. Proposed subparagraph (2)(B).

If an applicant certifies that any product or controlling use patent is invalid or will not be infringed, paragraph (3)(A) requires that it must give notice of such certification to either the owner of the patent or the representative of the patent owner who was designated under section 505 (b) or (c) of the Act, 21 U.S.C. 355 (b) or (c), as amended by this bill.

Paragraph (3)(B) requires that such notice state that a Paper NDA has been submitted to obtain approval of the drug to engage in the commercial manufacture, use or sale of the generic drug before the expiration of the patent which has been certified as invalid or not infringed.

Paragraph (3)(C) provides that if a Paper NDA is amended after submission to include a certification that a product patent or controlling use patent is invalid, notice of such certification must be given to the appropriate parties at the time the amended application is submitted.

Section 103(b) of the bill deals with the effectiveness of approval of a Paper NDA for a listed drug. Accordingly, section 505(c) of the Act, 21 U.S.C. 355(c), as amended by section 102(a)(2) of the bill, is

further amended to require the FDA to make approval effective as appropriate in light of relevant, patent-related circumstances.

If the applicant certified in the Paper NDA that no patent information was supplied or that the relevant patents have expired, approval of the Paper NDA may be made immediately effective. If the applicant certified on the basis of supplied information that the patent would expire on a specified future data, the Paper NDA may be approved and the approval becomes effective on that date.

Generally, if the applicant certifies that one or more of the product or controlling use patents were invalid or not infringed, approval of the Paper NDA becomes immediately effective. However, if within 45 days after receipt of notice of the certification of invalidity or non-infringement, an action for patent infringement regarding one or more of the patents subject to the certification is brought, approval of the Paper NDA may not be made effective until 18 months after the notice of certification was provided or a court decision issued. If the court finds the patent is valid or not infringed, then approval shall be effective on the date of the court's order. If the court decides the patent has been infringed an order under 35 U.S.C. 271(e) shall issue. Each party to the action has an affirmative duty to reasonably cooperate in expediting the action and the court may shorten or extend the 18-month period, as appropriate, when either party breaches that duty.

No action for a declaratory judgment with respect to the patent may be brought before the expiration of the 45 day period which begins with the giving of notice of the certification of patent invalidity or non-infringement. At the end of the 45 days, a suit for declaratory judgment regarding the patent in question may be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

Subparagraph (D) denies the FDA the authority to make effective the approval of a Paper NDA for a drug which contains an active ingredient (including any ester or salt of the active ingredient) that was approved for the first time in an NDA between January 1, 1982 and the date of enactment of this bill until 10 years after the date of approval of the NDA.

Section 104 of the bill adds a new subsection (1) to section 505 of the Act, 21 U.S.C. 355, which makes hitherto undisclosed safety and effectiveness information that has been submitted in an NDA available to the public upon request. Absent extraordinary circumstances, safety and effectiveness information and data shall be disclosed in the following circumstances: (1) if the NDA is abandoned; (2) if the FDA has determined that the NDA is not approvable and all legal appeals have been exhausted, (3) if approval of the NDA under section 505(c) of the Act, 21 U.S.C.A. § 355(c), has been withdrawn and all legal appeals have been exhausted, (4) if the FDA has determined that the drug is not a new drug, or (5) upon the effective date of approval of the first ANDA which refers to the drug or upon the date which an ANDA could have been approved if an application had been submitted.

Section 104 of the bill adds a new subsection (m) to section 505 of the Act, 21 U.S.C. § 355, to define the term "patent" to mean a patent issued by the Patent and Trademark Office of the Department of Commerce.

Section 105(a) of the bill requires the FDA to promulgate rules to implement new subsection (j). These rules, which shall be issued within one year of enactment of this bill, shall be promulgated in accordance with the informal rulemaking requirements of the APA, 5 U.S.C. 553.

Section 105(b) of the bill establishes an interim procedure for approving ANDAs for post-1962 drugs until the final regulations become effective. During the year following enactment of this bill, ANDAs for listed post-1962 drugs may be submitted in accordance with the current regulations applicable to pre-1962 pioneer drugs: 21 C.F.R. 314.2. In the event of inconsistencies between current regulations and the Act as amended by this bill, FDA shall follow the latter. However, the FDA may not approve an ANDA or Paper NDA under this interim procedure for a drug which is described in section 505(c)(3)(D) or section 505(j)(4)(D) of the Federal Food, Drug and Cosmetic Act.

Section 106 of the bill amends 28 U.S.C. 2201 to insert a cross reference indicating that certain declaratory judgment actions involving patents controversies cannot be brought except as authorized by this bill.

Title II—Patent Extension

Section 201 of the bill adds a new section 156 to title 35, to extend the normal 17 year term of a product, use, or process patent in the case of a patented product which is subject to pre-marketing clearance (as defined in this Act).

Under proposed section 156(a) the term of a patent which claims a product, a method of using a product, or a method of manufacturing a product is extended from its original expiration date if certain, specified conditions are met. The conditions that permit an extension of patent life are set forth in eight numbered paragraphs.

Paragraph (1) requires the patent to be in force at the time an application for extension is submitted to the Commissioner of Patents and Trademarks.

Paragraph (2) allows extension only if the term of the patent has never been extended. Thus, the extension authorized by the bill is a one time extension.

Paragraph (3) requires the application for extension to be submitted by the owner of record of the patent, or its agent, in accordance with the requirements of subsection (d), infra.

Paragraph (4), which consists of two subparagraphs, applies to product and use patents, not process patents. Subparagraph (A) permits a product or use patent to be extended if two requirements are met. First, the approved product has to be one that has not been claimed in another product patent which was issued earlier or which was previously extended. Second, the approved product and the use approved for the product may not have been identically disclosed or described in another product patent which was issued earlier or which was previously extended.

Subparagraph (B) permits a product patent to be extended notwithstanding that it would not qualify under subparagraph (A) under certain circumstances. In order to be extended in these cir-

cumstances, the holder of either of the two product patents must never have been and must never become the holder (i.e., patent owner or an exclusive licensee of the owner) of the other patent.

Paragraph (5) describes conditions applicable only to manufacturing method or process patents. Subparagraph (A) permits a process patent which does not primarily use recombinant DNA in the manufacture of the approved product to be extended if two conditions are met. First, no other patent has been issued which claims the product or a method of using the product and claims a method of using the approved product for any known therapeutic purpose. Second, no other method of manufacturing the product which does not use recombinant DNA technology in the manufacture of the product may be claimed in an earlier process patent.

Subparagraph (B) permits a process patent which primarily utilizes recombinant DNA in the manufacture of the approved product to be extended if several conditions are met. First, the holder of the process patent (I) is not the holder of the product or use patent; (II) is not owned or controlled by a holder of a product or use patent or by a person who owns or controls such a holder, and (III) does not own or control the holder of such a patent or a person who owns or controls a holder of such a patent. Second, no other method of manufacturing the product primarily using recombinant DNA technology is claimed in an earlier process patent.

Paragraph (6) authorizes an extension if the product which is claimed in the product patent has been subject to a regulatory review period before its commercial marketing or use.

Paragraph (7)(A) generally permits an extension if the approval after regulatory review is the first approval for commercial marketing or use of that product under an applicable Federal law.

Paragraph (7)(B) authorizes an exception to the first time requirement of paragraph (7)(A) in the case of an approved product made under a patented process which primarily uses recombinant DNA technology. An approved product of this kind can receive its second approval for commercial marketing or use provided that it is the first time a product made by the claimed process has been approved.

Paragraph (8) provides that in the case where two different approved products are the subject of the same patent, an extension will be granted only for the first approved product which has been the subject of a regulatory review period.

The balance of proposed section 156(a) defines as "approved product" when used elsewhere in the bill the product referred to in paragraphs (4), (5), (6) and (7), supra. Also, it defines the holder of a patent for purposes of paragraphs (4)(B) and (5)(B) as being any person who is the owner of record of the patent or who is the exclusive licensee of the owner of record of the patent.

Proposed section 156(b) extends all the rights of patent law to the patent during the period of extension subject to the following limitations:

> (1) When a product patent claiming the approved product is extended, the holder's rights are limited to any use of the approved product which was approved before the expiration of the extended term of the patent under the provision of law under which the applicable regulatory review period occurred.

(2) When a use patent claiming a method of using the approved product is extended, the holder's rights are limited to any use of the product which is claimed in the use patent and which was approved before the expiration of the extended term of the patent under the provision of law which the applicable regulatory review period occurred.

(3) When a process patent claiming a method of manufacturing the approved product is extended, the holder's rights are limited to the method of manufacturing which is claimed in the process patent and which is used to make the approved product.

Proposed section 156(c) prescribes the manner by which the length of the period of extension is determined. Generally, the length of the extension will coincide with the length of the regulatory review period in which the approved product was approved. The latter, however, shall be reduced for several reasons. First, each phase of the regulatory review period is reduced by any time that the applicant for extension did not act with due diligence during that phase. See (d)(2)(B), infra. Second, after any such reduction, only one-half of the time remaining in the testing phase shall be added to the time remaining in the approval phase to comprise the total period eligible for extension, except that total patent term may not exceed 14 years.[16]

Proposed section 156(d) sets forth procedures for applying for an extension. To obtain an extension, subsection (d)(1) requires the patent owner or its agent submit an application to the Commissioner of Patents and Trademarks within 60 days of approval of the approved product. The application shall contain the following information:

(A) the identity of the approved product;

(B) the identity of the patent to be extended and identification of each claim of that patent which claims the approved product or a use or process of the approved product;

(C) the identity of every patent known to the owner that claims or identically discloses the approved product or a use or process of the approved product;

(D) the identity of all other products approved under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use and which are associated with claims disclosed in subparagraph (C), supra;

(E) information that would enable the Commissioner to determine the eligibility of a patent for extension and the rights that will derive from the extension as well as information to the FDA to determine the period of extension;

(F) a brief description of the activities undertaken by the applicant during the regulatory review period with respect to the approved product and when; and

(G) any other information the Commissioner may require.

Subsection (d)(2)(A) provides that within 60 days of the submission of an application, the Commissioner notify the Secretary of

[16] Section 156(g)(4), infra, adds further limitations on the period of extension depending on whether the approved product was developed before or after the date of enactment of this bill.

HHS (relating to drug products, devices and food additives which are subject to the Federal Food, Drug, and Cosmetic Act) to review the dates contained in the application for the regulatory review period. Within 30 days, the Secretary shall make a determination as to those dates, notify the Commissioner, and publish them in the Federal Register.

Subsection (d)(2)(B) authorizes any interested person to petition the Secretary for a determination regarding whether the applicant for an extension acted with due diligence during the regulatory review period of the appproved drug. The petition must be submitted within 180 days of the publication by the Secretary of a determination of the regulatory review period and must state that the applicant did not act with due diligence (defined in subsection (d)(3)), infra, during some part of the regulatory review period. The Secretary has 90 days to make a decision on the matter raised by the petition. The Secretary of HHS cannot delegate the authority to decide the merits of the petition to any office below that of the Commissioner of the FDA.

After making the determination, the Secretary shall notify the Commissioner of Patents and Trademarks and publish the decision in the Federal Register. Any interested person may request an informal hearing within 60 days of publication of the determination. If a timely request is made, the Secretary must hold a hearing within 30 days, give notice of the hearing to the patent owner and any interested person, and provide them with an opportunity to participate. Within 30 days of the hearing, the Secretary must affirm or revise the determination, notify the Commissioner of Patents and Trademarks, and publish it in the Federal Register.

"Due diligence" is defined to mean "that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period."

The applicant for an extension is subject to any disclosure requirements prescribed by the Commissioner of Patents and Trademarks.

Proposed section 156(e) provides that the Commissioner's determination that a patent is eligible for extension is to be made *solely* on the basis of information contained in the application. If it is determined that the patent is eligible for an extension, the Commissioner shall issue a certificate of extension, under seal, for the period determined, in accordance with procedures authorized by subsection (c). The certificate shall be recorded in official patent files and becomes a part of the original patent.

In the event that the original term of the patent for which extension is sought will expire before a final decision by the Commissioner on that extension, the Commissioner may issue an interim extension certificate for a period of up to one year.

Proposed section 156(f) contains the definitions of various terms for purposes of that section.

The term "product" is defined in subsection (f)(1) to include a drug product and any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

The term "human drug product" is defined in subsection (f)(2) to mean the active ingredient of a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act), including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

The term "major health or environmental effects tests" is defined in subsection (f)(3) to mean a test which is reasonably related to the evaluation of the health or environmental effects of a product, which requires at least six months to conduct, and the data from which is submitted to receive permission for commercial marketing or use. Periods of analysis or evaluation of tests results are not to be included in determining if the conduct of a test required at least six months.

Subsection (f)(4)(A) states that any reference to section 351 means section 351 of the Public Health Service Act, 42 U.S.C.A. 262, relating to the regulation of biological products.

Subsection (f)(4)(B) states that any reference to section 503, 505, 507, or 515 is a reference to section 503, 505, 507, or 515 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. sections 353 (relating to exemptions of drugs and devices from labeling requirements when processed, labeled, or repacked by other than the original processor), 355 (introductory or premarketing clearance procedure), 357 (relating to the certification of drugs containing penicillin, streptomycin, chlortetracycline, chloramphenical, bacitracin or any other antibiotic drug), 360b (relating to new animal drugs, and 360e (relating to premarketing approval of a class III device).

The term "informal hearing" is defined in subsection (f)(5) to have the same meaning as prescribed for such term by section 201(g) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 (cf. APA, 5 U.S.C. 554, 556, 557).

The term "patent" is defined in subsection (f)(5) to mean a patent issued by the United States Patent and Trademark Office.

Proposed section 156(g) provides various definitions of the term "regulatory review period". Although it differs for each product that can be the subject of patent extension, the regulatory review period consists of a testing phase and an agency approval phase. As respects drug products, food and color additives, and medical devices, the term "initially submitted" is used to describe the date when the testing phase is completed and the agency approval phase begins.

Under section 156(g)(1) the regulatory review period for drug products is the sum of the periods: (1) beginning when an exemption under 505(i) or 507(d) was granted and ending when the initial submission of an application for approval under section 351 of the Public Health Service Act, 505, 507, of the Federal Food, Drug, and Cosmetic Act; and (2) beginning when an application for approval was initially submitted under the mentioned laws and ending when the application was approved.

Under section 156(g)(2) the regulatory review period for food and color additives is the sum of the periods: (1) beginning when a major health or environmental effects tests for a food or color additive was initiated and ending when a petition requesting the issuance of a regulation for use of the additive was initially submitted;

and (2) beginning when a petition for the issuance of a regulation was initially submitted and ending when the regulation became effective.

However, if permission for commercial marketing was delayed because objections were filed to the regulation, or if such permission was initially granted and later revoked before actual marketing began because objections were filed to the regulation, the period described above would end when the objections were resolved and commercial marketing was permitted.

Under section 156(g)(3) the regulatory review period for medical devices is the sum of the periods: (1) beginning when human clinical investigations were commenced and ending when an application for approval was initially submitted; and (2) beginning when an application for approval was initially submitted and ending when the application was approved, or beginning when a notice of completion of a product development protocol was initially submitted and ending when the protocol was declared completed.

Section 156(g)(4), provides different maximum periods depending on whether the approved product was developed before or after the date of enactment of this bill.

Under (g)(4),[17] the total period of regulatory review which can be counted towards extension shall not exceed five years when: (1) the patent to be extended was issued after the date of enactment of this bill; or (2) the patent was issued before the date of enactment of this bill, but the approved product's regulatory review period had not begun on the date of enactment of this bill. The total period of eligible regulatory review would not exceed two years when: (1) the patent to be extended was issued before the date of enactment; and (2) the approved product's regulatory review period had begun before the date of enactment but the product had not been approved by that date.

Proposed section 156(h) authorizes the Commissioner of Patents and Trademarks to establish such fees as he or she determines appropriate to cover the costs to his or her office of receiving and acting upon application for patent extensions.

Section 201(b) of the bill amends the analysis of chapter 14 of 35 U.S.C. to add a reference to section 156 "Extension of patent time" authorized by section 201(a) of the bill.

Section 202 of the bill amends 35 U.S.C. 271 relating to patent infringement, to add a new subsection (e).

Proposed subsection (e)(1) provides that it shall not be an act of infringement to make, use, or sell a patented invention solely for uses reasonably related to the development and submission of information under a federal law which regulates the approval of drugs.

Proposed subsection (e)(2) provides that it shall be an act of patent infringement to submit an ANDA for a drug (1) which is claimed in a valid product patent, or (2) a use of which is claimed in a valid use patent, if the purpose of submitting the ANDA is to get its approval with an effective date prior to the expiration of such patent.

[17] Additional restrictions are found in proposed section 156(c)(2).

In an infringement action pursuant to section 271, of the law, no injunctive or other relief may be granted to prohibit the activity which is authorized by subsection (e)(1).

Proposed subsection (e)(4) makes certain remedies available and exclusive in the event a patent is valid and has been infringed pursuant to subsection (e)(2). The court must order the effective date of any ANDA relating to a drug involved in the infringement to be a date not earlier than the expiration date of the infringed patent. Injunctive relief may be granted to prevent commercial marketing under an approved ANDA and monetary damages or monetary relief are authorized when commercial marketing has begun.

CONSTITUTIONALITY OF SECTION 202

The provisions of section 202 of the bill have the net effect of reversing the holding of the court in *Roche Products, Inc.* v. *Bolar Pharmaceutical Co., Inc.*, — F.2d, — No. 84-560, slip op. (Fed. Cir. April 23, 1984). Opponents of the bill have suggested that section 202 raises serious constitutional issues. The Committee has examined those issues and concluded that the provisions in the bill are sound and constitutional.[18]

[18] This view is consistent with the opinion of the Library of Congress, American Law Division:

CONGRESSIONAL RESEARCH SERVICE, THE LIBRARY OF CONGRESS, WASHINGTON, DC, JULY 24, 1984

To: House Judiciary Committee, Subcommittee on Committee on Courts, Civil Liberties, and the Administration of Justice (Attn: David Beier).

From: American Law Division.

Subject: Constitutional Objections to Section of Patent Term Restoration Bill to Define Use.

This memorandum responds to your request to review and assess the constitutional objections raised to § 202, of H.R. 3605, the patent term restoration bill. Because of time constraints, this memorandum is necessarily brief.

In § 202, Congress would provide that it is not an infringement to make, use, or sell a patented invention solely for uses reasonably related to the development and submission of information for the purpose of obtaining FDA premarketing approval of a drug. The purpose of the provision is to overturn the ruling in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F. 2d 858 (C.A.F.C. 1984). That case held that Bolar infringed a patent owned by Roche when, during the patent term, Bolar used the patented substance to prepare a submission to FDA for the purpose of enabling Bolar to market the drug after the patent expired. Crucial to the decision was the court's interpretation of the word "uses" in 35 U.S.C. § 271(a), which makes it an infringement for anyone who without authority "makes, uses or sells any patented invention". Congress has never defined "uses", the court in *Roche* acknowledged; it has gained meaning through judicial elucidation, but the courts have never applied the word to bar every use. *Id.*, 861. And, insofar as it appears from the opinion, the court's ruling is the first case to determine whether Roche's use was a proscribed use within the meaning of § 271(a). In fact, the district court decision overturned by the appeals court was that no infringement had occurred.

It has been objected before the Subcommittee that, in its application to existing patents, § 202 would constitute a "taking" under the Fifth Amendment which would mandate "just compensation" to the patent holder. Of course, it is clear that a patent is property and thus if it were taken for a public use compensation would have to be paid. See, e.g., *Hartford-Empire Co. v. United States*, 323 U.S. 386, 415 & n. 11 (1945). But the threshold question is whether there is a "taking" or whether there is a permissible regulation. Indeed, the Court has never clearly established the standards for applying a "taking" analysis or a due process analysis to regulation that necessarily diminishes the value of property held by someone. Thus, the first question that must be asked is whether § 202 should be analyzed in the context whether it constitutes a "taking" or whether it should be evaluated as a regulation of property, and it is not at all clear that the "taking" analysis chosen by the Subcommittee witnesses is the correct one.

Difficulty in distinction has arisen because the Court has not drawn the line where it could easily be applied. That is, a taking might be deemed to occur only when the government has physically appropriated one's property and transferred it elsewhere. See, e.g., *Hawaii Housing Auth. v. Midkiff*, 104 S. Ct. 2321 (1984). Due process analysis could then be applied to any police power regulation that diminished the value of property. See, e.g., *PBGC v. R. A. Gray & Co.*, 88-245 (June 18, 1984). However, at least since *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922), it has been a maxim "that while property may be regulated to a certain extent, if regulation goes too far it will be recognized as a taking." Having permitted the blurring thus of the line, the Court has not enunciated clear standards by which we may discern when one or the other analysis applies. See, e.g., *Penn Central Transp. Co. v. City of New York*, 438 U.S. 104, 120-122 (1978); *Pruneyard Shopping Center v. Robins*, 447 U.S. 74, 82-84 (1980).

Our reason for suggesting that, perhaps, a due process analysis is the more appropriate one springs from a look at what it is § 202 does. The basis of the section apears to be a conclusion that *Roche* was wrongly decided, that Congress did not intend the word "uses" in § 271(a) to extend so broadly. Congress has previously legislated to change what it perceived to be incorrect judicial decisions and in so doing has adversely affected property rights of the prevailing side in those cases. For example, in the "portal to portal" cases, the Supreme Court held that "work week," which Congress had not defined, in the FLSA included a vast amount of preliminary and incidental activities of employees in connection with their work, exposing employers to considerable unexpected expense. *Tennessee Coal Co. v. Muscoda Local*, 321 U.S. 590 (1944); *Jewell Ridge Corp. V. Local No. 6167*, 325 U.S. 161 (1945); *Anderson v. Mt. Clemens Pottery Co.*, 328 U.S. 680 (1946). Congress thereupon passed a law changing the rulings and wiping out the substantive liabilities owed by employers under the decisions. The lower courts uniformly ruled against challenges that the act's retroactive operation destroyed vested rights in violation of the due process clause. E.g., *Battaglia v. General Motors Corp.*, 169 F. 2d 254 (C.A. 2), *cert. den.*, 335 U.S. 887 (1948); *Thomas v. Carnegie-Illinois Steel Corp.*, 174 f. 2d 711 (C.A. 3, 1949). While the Supreme Court itself never reviewed the act on the merits, it did, on timely motion, after it had denied *certiorari* to a case applying its earlier rulings, revoked its denial of *certiorari* and remanded to permit consideration by the district court of the new act, which had the effect of nullifying the prior judgment.

149 Madison Avenue Corp. v. Asselta, 331 U.S. 795 (1947). On subsequent reconsideration, see 79 F. Supp. 413, 90 F. Supp. 442 (S.D.N.Y., 1948, 1950).

Just recently, the Supreme Court has affirmed, not in the context of legislative revision of a judicial ruling, that, if "the retroactive application of a statute is supported by a legitimate legislative purpose furthered by rational means," it passes the due process test. *PBGC v. R. A. Gray & Co., supra.* In that case, the Court sustained an ERISA provision imposing liabilities for employer withdrawals from a multiemployer pension plan which was made retroactive to April 29, 1980, although the law was not enacted until September 26, 1980. The employer withdrawal from the plan on June 1, 1980, permissible when it was accomplished, thus became impermissible because of the retroactivity of the provision. See also *Usery v. Turner-Elkhorn Mining Co.*, 428 U.S. 1 (1976) (sustaining imposition upon employers of cost of industrial illnesses contracted while in employer's workforce prior to enactment of act as a permissible means of allocating costs); *United States v. Darusmont*, 449 U.S. 292 (1981) (upholding retroactive tax).

Thus, whether Congress views § 202 as a correction of a judicial misreading of a prior law or as a rational means of pursuing the public good through regulation of existing property rights, there is considerable judicial precedent to sustain the provision under the due process clause as an exercise of the police power.

On the other hand, similarly there is precedent to sustain the validity of an enacted § 202 under a " taking" challenge. The section in reality would modify an advantage that derives not from the patent law in and of itself but from the operation of law respecting FDA approval of drugs before they can be marketed. If one must wait until expiration of the patent to use the patented item to develop the necessary tests results for submission to FDA for its approval, the lapse of time between testing through submission to approval to marketing is likely to be a period of years, all of which time the original patent holder enjoys the benefit of his patent past its expiration date.

Much reliance was placed during the hearing on *Ruckelshaus v. Monsanto Co.*, 83-196 (June 26, 1984), as establishing the validity of the taking challenge. The reverse appears to be the case. *Monsanto* involves, in its relevant aspect here, disclosure provisions of FIFRA under which companies were required to submit data, including trade secrets, to obtain regulatory approval for marketing and under which data, including trade secrets, could be disclosed. During the period for which the Court held a taking could occur through disclosure, federal law specifically prohibited disclosure. Trade secrets, the Court held, were property under state law. That being so, the Court was concerned with whether a taking had occurred through disclosure. It admitted that regulation resulting in economic injuries could be deemed a taking only through an "ad hoc, factual" inquiry, under which the Court was to consider such factors as "the character of the governmental action, its economic impact, and its interference with reasonable investment-backed expectations." The latter factor was determinative to the Court. For the period when legislation guaranteed against disclosure, the firm had a justifiable expectation that its submissions would not be disclosed; its investment-backed expectations were, in other words, objectively sound. For the other periods, when legislation was either silent or ambiguous or when it specificially permitted disclosure, the firm could not have relied on any expectation of secrecy and when it submitted the data it gave up its expectancy.

With respect to § 202, we have much the same situation that existed in FIFRA prior to 1972. There, the law itself was silent but it was arguable that the Trade Secrets Act, 18 U.S.C. § 1905, afforded the firm protection. Only in *Monsanto* itself, 12 years after the last year in which the Trade Secrets Act could have been the basis of reliance, did the Court hold that Act inapplicable. If Monsanto did rely on it, the firm was mistaken; its expectancy was unjustified. Here, we have a judicial interpretation of a word in the patent laws which was unsettled previously and which because of the possibility of Supreme Court review or congressional alteration remains unsettled.

The difference in the degree to which investment-backed expectations were justifiable in *Monsanto* and appear to be less justifiable as respects § 202 seems to be significant and lessens the reliance of witnesses on *Monsanto*.

With regard to the other two factors mentioned in *Monsanto*, they too seem to suggest in their applicability the defensibility of § 202. The second factor was "economic impact" of the governmental action. Without reviewing extensively the cases in which a taking challenge was denied despite a substantial economic loss to the regulated entity, it can be said that generally the Court holds that if the regulated entity still has a profitable use for his property, even if not the

best use, the most profitable use, no taking will be found. Thus, in *Andrus v. Allard*, 444 U.S. 51 (1979), the Court observed that while the owners could not sell the articles they could display them and make some profit. Loss of future profits was not viewed as a serious threat of harm. Similarly, in the *Penn Central case, supra*, while the owners were deprived of the most profitable use, the property was still economically viable.

Here, § 202 does not in the least touch upon the economic worth of the patents during the terms of the patents. They retain all the value the holders had in them. What the provision does is remove or reduce the economic value inhering in the period after expiration when other companies are starting up and processing their goods.

The third factor is the character of the governmental action. That character in this instance appears to be a pure police power kind of regulation which the government pursues in numerous instances to improve and protect the public health and safety, i.e., the promotion of increased numbers of medicines and drugs on the market to the benefit of health and price competition. The character, thus, is like the regulation approved in *Penn Central, supra*, and unlike the action disapproved in *Kaiser Aetna v. United States*, 444 U.S. 164 (1979).

In conclusion, while the constitutionality of § 202 is far from a settled question, it does appear that respectable precedent exists by which to sustain it under the Fifth Amendment challenge, whether as a taking or a denial of due process.

JOHNNY H. KILLIAN, *Senior Specialist, American Constitutional Law.*

It is alleged by some witnesses that the provisions of the bill which permit the limited testing of drugs while they are on patent in order to assist in the preparation of an abbreviated new drug application is a "taking" without just compensation in violation of the requirements of the Fifth Amendment. As the Supreme Court itself has said regarding determinations of whether legislation or other acts of government constitute a taking:

> this Court, quite simply, has been unable to develop any "set formula" for determining when "justice and fairness" require that economic injuries caused by public action be compensated by the government. *Penn. Central Transp. Corp.* v. *New York City*, 438 U.S. 104, 124[1] (1978) (hereinafter *Grand Central*).

The Court has identified several factors for consideration in such cases: the economic impact of the action and the character of the government action. *Grand Central, supra*, at 124. Particularly important in this assessment is whether the interference with the property right arises from a "public program adjusting the benefits and burdens of economic life to promote the public good". *Grand Central, supra.*

In this case the benefits to the government and the general citizenry will be substantial. As a result of section 202 generic drugs will be able to be placed on the market between 18 months and 2 years earlier than without this provision. The availability of such generic substitutes will assist in the reduction of health care costs. In view of the high percentage of individual income devoted to medical costs, these reductions will be especially important to the poor, the under-insured, and the elderly. The government itself, as purchaser of prescription drugs, will also save money as a result of this amendment.

On the other hand, the competing claim of the pioneer drug companies holding the patents on these drugs seems much less tangible. As the Court of Appeals for the Federal Circuit itself said in *Roche*, the Congress has never had occasion to define the term "use". Thus, the Congress has never had occasion to evaluate the competing policy considerations presented by this bill. In addition, until the *Roche* case itself there never was an appellate case dealing with this question. Therefore, it is not altogether clear that the

1. 98 S.Ct. 2646, 57 L.Ed.2d 631.

"distinct investment backed expectations" of pioneer drug company patent holders are all that settled.

Assuming for the sake of argument that such "expectations" are settled, the Supreme Court has also suggested that Congress examine the nature of the governmental interference.[19] Just this term the Court said "legislation readjusting rights and burdens is not unlawful solely because it upsets otherwise settled "expectations". *Pension Benefit Guaranty Corp.* v. *R. A. Gray & Co.*, 52 U.S.L.W. 4810 (June 18, 1984).

In this case the generic manufacturer is not permitted to market the patented drug during the life of the patent; all that the generic can do is test the drug for purposes of submitting data to the FDA for approval. Thus, the nature of the interference is *de minimus*. To hold otherwise would be to protect the pioneer drug company from competition for a period of up to 2 years after the patent has expired.

The nature of the interference with patent rights created by this bill is necessitated by the very nature of the industry involved. For example, in the automobile industry there would be no need to permit testing of a patented auto engine before a patent expires because—unlike the FDA in the drug area—there is no government regulatory agency in place which would delay marketing of that new product and prevent competition once the patent has expired.

In this case the Committee has merely done what the Congress has traditionally done in the area of intellectual property law; balance the need to stimulate innovation against the goal of furthering the public interest.[20] Just as we have recognized the doctrine of fair use in copyright, it is appropriate to create a similar mechanism in the patent law. That is all this bill does.

Section 203 of the bill amends 35 U.S.C. 282, relating to the presumption of validity and available defenses in a patent infringement suit, to add a new defense. An improper grant of patent extension, or any portion thereof, because of a material failure by the applicant or by the Commissioner of Patents and Trademarks to comply with the requirements of proposed section 156, is a defense in any action involving the infringement of the patent during the period of patent extension. However, a due diligence determination made under proposed section 156(d)(2) is not subject to review in a patent infringement action.

The bill reported by the Committee on Energy and Commerce amends the purpose line of this bill to include a reference to title II, i.e., patents, as well as title I, drugs, to wit: "A bill to amend the Federal Food, Drug, and Cosmetic Act to revise the procedures for new drug applications and to amend title 35, United States Code, to authorize the extension of the patents for certain regulated products, and for other purposes."

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[19] The situation presented in H.R. 3605 does not result in the total extinguishment of the patent owner rights, because the patent owner still maintains a right to exclude others from the commercial marketplace. Thus, the bill creates a situation similar to the statute upheld in *Andrus* v. *Allard*, 444 U.S. 51, 65-66 (1979), and unlike that questioned in *Ruckelshaus* v. *Monsanto Corp.*, 83-196 (U.S. Sup. Ct. June 26, 1984).

[20] It is important to note that most patent holders affected by section 202 will also receive a benefit from the bill in the form of patent term extension. This type of exchange of property interests was upheld by the court in the *Grand Central* case, albeit in a different context.

OVERSIGHT FINDINGS

The Committee makes no oversight findings with respect to this legislation.

In regard to clause 2(1)(3) (D) of rule XI of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Operations.

NEW BUDGET AUTHORITY

In regard to clause 2(1)(3)(B) of rule XI of the Rules of the House of Representatives, H.R. 3605 creates no new budget authority or increased tax expenditures for the Federal Government.

INFLATIONARY IMPACT STATEMENT

Pursuant to clause 2(1)(4) of rule XI of the Rules of the House of Representatives, the Committee finds that the bill will have no foreseeable inflationary impact on prices or costs in the operation of the national economy.

FEDERAL ADVISORY COMMITTEE ACT OF 1972

The Committee finds that this legislation does not create any new advisory committees within the meaning of the Federal Advisory Committee Act of 1972.

COST ESTIMATE

In regard to clause 7 of rule XIII of the Rules of the House of Representatives, the Committee agrees with the cost estimate of the Congressional Budget Office and estimates that the additional cost to the government which will be incurred as a result of enactment of this bill is set forth in the CBO cost estimate.

STATEMENT OF THE CONGRESSIONAL BUDGET OFFICE

Pursuant to clause 2(1)(3)(C) of rule XI of the Rules of the House of Representatives, and section 403 of the Congressional Budget Act of 1974, the following is the cost estimate on H.R. 3605 prepared by the Congressional Budget Office.

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC.

Hon. PETER W. RODINO, Jr.,
Chairman, Committee on the Judiciary, U.S. House of Representatives, Rayburn House Office Building, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has reviewed H.R. 3605, the Drug Price Competition and Patent Term Restoration Act of 1984, as ordered reported by the House Committee on the Judiciary on July 31, 1984.

We estimate that enactment of this bill could result in increased personnel costs to the federal government of approximately $2.2 million annually. The bill, however, does not specifically authorize additional appropriations for the Food and Drug Administration (FDA) or the United States Patent and Trademark Office (PTO).

This bill may also result in savings if cheaper, generic drugs are made available for purchase by the federal government. These savings would occur in various programs throughout the budget such as Medicare, Medicaid, and the Veterans Administration. However, the magnitude of these savings is unknown.

TITLE I

Title I of this bill would allow drug manufacturers to use an abbreviated new drug application (ANDA) when seeking approval to make generic copies of drugs that were approved by the FDA after 1962. An estimated 150 drug products approved after 1962 are currently off patent and would become available for generic copy using the ANDA procedure proposed in this bill.

The FDA estimates that the enactment of H.R. 3605 would at least triple the workload of the division responsible for approving ANDAs. Currently, this division reviews ANDAs for generic copies of pre-1962 approved drug products. The workload would increase as several manufacturers file an ANDA for each drug product that becomes available for generic copy. Because they would be reviewing information on new drugs, the FDA believes it would take them a year to process each of the new applications. This is about three months longer on average than it currently takes to process a pre-1962 ANDA. FDA expects an increased workload in other areas as well from carrying out the activities described in the bill. We estimate that implementing Title I could cost the FDA about $1.5 million. The actual cost to the federal government would depend on the extent to which FDA would expand to accommodate the increased workload.

Enactment of this legislation could also result in savings to the federal government. In fiscal year 1983, the federal government spent approximately $2.4 billion for drugs in the Medicaid program, and in veteran and military hospitals. Data on drug costs in the Medicare program are unavailable. If the federal government is currently purchasing these 150 copiable drug products at higher, brand name prices, savings may result if lower priced, generic copies of these drugs are substituted.

It is difficult to know in advance which if the available 150 drug products manufacturers would choose to copy. It is also difficult to estimate the price at which these generic copies would be sold. Generic versions of ten popular drug products show their price to be on average 50 percent less than their brand name equivalent. The dollar amount the federal government currently spends on these 150 brand name drug products is unknown.

TITLE II

Title II of this bill would extend the amount of time for which certain patents are issued to include some or all of the time required for a manufacturer to test a product for safety and efficacy and to receive marketing approval. Products affected by this legislation would be drugs, medical devices, and food and color additives.

The activities described in Title II of this bill would be performed by both the FDA and the PTO. FDA would be responsible for deter-

mining the applicable regulatory review period for a product used in setting the length of the patent extension. FDA would also monitor diligence in product testing which must be shown in order for a manufacturer to receive the maximum possible patent extension. FDA estimates it would cost them $0.7 million to implement these provisions. PTO would be responsible for handling patent extension applications and for determining extension eligibility. The bill states that the PTO Commissioner may charge manufacturers a fee to cover the cost of receiving and acting upon applications. Additional costs to PTO would be less than $500 thousand.

STATE AND LOCAL GOVERNMET IMPACT

Enactment of this bill would not directly affect the budgets of state or local governments. To the extent that these governments purchase drugs, they may realize savings if cheaper, generic drugs are made available by this bill. The magnitude of these potential savings is unknown.

PREVIOUS CBO ESTIMATE

On June 19, 1984, CBO prepared a cost estimate for H.R. 3605 as ordered reported by the House Committee on Energy and Commerce. In terms of the cost to the federal government, the two versions of the bill are the same except that Title II of the Energy and Commerce bill also applied to animal drugs and veterinary biological products. In the previous estimate, however, we showed potential increased personnel costs to the federal government of $1.1 million. FDA has since more carefully studied the possible affects of this bill on their agency. Given this new information, we believe that personnel costs could increase by $2.2 million as a result of enactment of this legislation.

Please call if I can be of additional assistance or members of your staff may wish to contact Carmela Pena (226-2820) of our Budget Analysis Division for further details on this estimate.

Sincerely,

RUDOLPH G. PENNER, *Director.*

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ADDITIONAL VIEWS

We are supportive of many of the ideas contained in H.R. 3605 which the Judiciary Committee worked on and developed last Congress. However, changes made by the Committee on Energy and Commerce will have a substantial effect on the Patent and Trademark Office and a substantial effect on a patent owners' ability to protect his invention.

H.R. 3605 reflects a compromise worked out by Congressman Waxman between the Pharmaceutical Manufacturers Association, representing the pharmaceutical industry and the generic drug industry. Eleven major drug companies did not go along with that compromise.

H.R. 3605 as drafted would place a heavy administrative burden on the Patent and Trademark Office. Congressman Hughes with the support of Chairman Rodino, Mr. Fish, Mr. Moorhead and others tried to correct this with an amendment that lost with bipartisan support on a record vote of 16 opposed and 13 in favor.

This amendment would not seriously alter the basic compromise reached by Mr. Waxman but it's particularly important to the Patent Office. In an overabundance of caution the Commerce meeting overreacted to a non-problem. The private patent bar told the Judiciary Committee Subcommittee that so-called "evergreening" is not a problem. The Patent Office looked into it and reported back that it's not a problem. No creditable information was submitted to the Subcommittee showing that drug firms obtain a chain of patents relating to the same product for the purpose of prolonging their patent.

But in spite of all of this H.R. 3605 provides three pages of procedures requiring the Commissioner to make a determination as to whether a particular patent could be eligible for an extension which is equivalent to an evaluation for which his examiners are not now trained. Regardless of what some have said the role of the Commissioner is not ministerial and would require a specially trained staff to handle these determinations.

In addition, the amendment would modify the present policy reflected in H.R. 3605 that generally only the first patent claiming the product or fully disclosing that product and its approved use be rewarded with an extension. Our solution achieves substantially the same result, but is much simpler to administer and much fairer to patent holders. Present practice provides that when you file for a patent it's usually for one of three different types of patent: a patent on the product which is the most valuable, a patent for a particular type of use and/or a patent for the process by which something is made. You may obtain one or all three of these patents depending on what type of patent is involved and whether they meet the tough standards required in order to obtain a patent. What usually happens is that a person receives a patent

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on the product and a patent on a particular use of that product. Later a new use is discovered and a new patent obtained. Under H.R. 3605 you cannot receive an extension on the new use discov-

ered but only on the earliest issued patent. This will discourage research and innovation. Under our amendment should another later patent, such as one for a new use of an old product, undergo a subsequent regulatory review, it would be eligible for an extension.

This amendment is supported by the Department of Commerce, by the Patent and Trademark Office, American Intellectual Property Law Association, and bar groups from around the country.

These concerns warrant further consideration in the event that amendments are offered on the Floor of the House.

WILLIAM J. HUGHES.
PETER W. RODINO, JR.
JACK BROOKS.
SAM B. HALL, JR.
HENRY J. HYDE.
HAL SAWYER.
THOMAS N. KINDNESS.
CARLOS J. MOORHEAD.
HAMILTON FISH, JR.
DAN LUNGREN.
F. JAMES SENSENBRENNER, JR.
GEORGE W. GEKAS.
MICHAEL DEWINE.

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ADDITIONAL VIEWS

In addition to the amendment that may be offered on the Floor by Congressman Hughes (explained elsewhere in this report) which we very much support, we also intend to offer three other amendments that are critical if we are to maintain our present patent system as the central motivating force to invent which it has been for almost two hundred years. Mr. Moorhead will offer one amendment relating to the reversal of *Roche Products, Inc.* v. *Bolar Pharmaceutical Co., Inc.* and Mr. Sawyer will offer two amendments relating to the filing of an Abbreviated New Drug Application and the eighteen month marketing delay period.

Mr. Moorhead's amendment will be to Sec. 202 of the bill.

The present provision of section 202 of H.R. 3605 would add paragraphs (e)(1) and (3) to section 271 of title 35, United States Code, thereby overruling the recent decision of the Court of Appeals for the Federal Circuit in *Roche Products, Inc.* v. *Bolar Pharmaceutical Co., Inc.* (Fed. Cir., April 23, 1984). In that case, the court held that use of a drug patented by another, in preparation for marketing the drug after the patent expired, constituted patent infringement. The present language of H.R. 3605 would establish a "commercial use exception" to the fundamental rights of patent owners and would make that exception apply retroactively. Because of the many problems which may result from such sweeping language, our amendment takes a different and more limited approach.

First, instead of providing an outright commercial use exception during the life of all drug patents, this amendment would require that a patentee, applying for an extension of a drug patent, waive certain rights of exclusivity in the application for extension. Thus, any limitation on exclusivity would only apply to patents whose term had been extended and not apply retroactively. As testimony of Professor Dorsen and others pointed out at the hearings, retroactive modification of the exclusive rights awarded a patent holder without payment of just compensation may constitute an unconstitutional taking of property.

Second, the waiver of exclusivity would be effective only during the last year of the extended term of the patent.

Third, the waiver of all remedies against infringement of the patent during the final year of the extended term would apply only for uses directly related to the development and submission of information under a federal law regulating the manufacture, use or sales of drugs.

This amendment is a compromise. It reverses the *Bolar* decision but in such a way so as to avoid the problems created in H.R. 3605.

Mr. Sawyer's first amendment will simplify the notice provisions and guarantee added certainty by making a single event—filing of a complete application—the mandatory notice date. It replaces language which would have permitted an applicant to give notice on

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the date of submission of an Abbreviated New Drug Application (ANDA).

H.R. 3605 permits the ANDA applicant, in effect, to compel the patent owner to commence litigation on the validity of a patent within 45 days of receiving notice of the submission of an ANDA application, whether complete or not. This amendment safeguards patent owners from premature defenses of their patent rights that could create needless litigation and divert and drain resources. Patent litigation would not be permitted until after the generic manufacturer has at least demonstrated a legitimate interest in a drug by investment in preparing a complete ANDA. This complete filing requirement parallels the requirement applicable to full New Drug Applications (NDA) that a filing must be complete before being given full consideration. The effect of the amendment is that the trigger mechanism can occur only upon the acceptance of an ANDA or paper NDA as complete. As used in the context of the Federal Food, Drug, and Cosmetic Act, this means acceptance for "filing" by FDA of a complete application.

Mr. Sawyer's second amendment will make clear that FDA cannot approve an Abbreviated New Drug Application (ANDA) or a paper New Drug Application (NDA) where the validity of a patent covering that drug is being challenged in patent litigation until after the trial court enters its final judgment or such other period as the trial court may determine because one of the parties is being dilatory. It eliminates the requirement in the current bill directing FDA to permit the marketing of a generic copy eighteen months after the initiation of the patent infringement litigation.

This amendment also provides that, where a district court's determination that a patent is invalid is reversed on appeal, the case must be remanded to the district court with instructions to enjoin further sale of the infringing product during the remaining life of the product.

Under our system of law, patents are presumed valid. By contrast, H.R. 3605 would direct FDA to approve an ANDA or a paper NDA for a generic copy while litigation testing the validity of the patent is still ongoing. Except in those cases where the pioneer manufacturer is unduly delaying the litigation in order to keep a generic drug off the market, no ANDA or paper NDA should be made effective until the patent has expired or has been held to be invalid.

We urge you to support these amendments.

CARLOS J. MOORHEAD.
HAL SAWYER.
DANIEL E. LUGREN.
HAMILTON FISH, JR.
THOMAS N. KINDNESS.
F. JAMES SENSENBRENNER, JR.
MICHAEL DEWINE.

SENATE REPORT NO. 98-529

Much of the text of Title III of this Public Law is derived from S. 1816, as reported in the Senate. The report to accompany S. 1816 (S.Rep. No. 98-529, Committee on Commerce, Science, and Transportation, June 25, 1984) is set out:

[page 1]

The Committee on Commerce, Science, and Transportation, to which was referred the bill (S. 1816) to amend the Textile Fiber Products Identification Act, the Tariff Act of 1930, and the Wool Products Labeling Act of 1939 to improve the labeling of textile fiber and wool products, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and an amendment to the title and recommends that the bill do pass.

PURPOSE OF BILL

The objectives of S. 1816, as reported, are to clarify and improve country-of-origin labeling requirements for textiles and increase consumer awareness at the time of purchase of the product's country of origin. By using "time of purchase", the Committee is referring to the point in time the consumer pays for or promises to pay for an item and thereby receives an interest in the item.

The bill requires conspicuous country of origin labeling on domestic and foreign-made textile, fiber and wool products. Country-of-origin information is also required in mail order promotional descriptions for textile, apparel and wool products sold in the United States.

LEGISLATIVE HISTORY

P.L. 98-417

Background and Needs

Country-of-origin labeling is now required by the Textile Fiber Products Identification Act. This law is enforced by the Federal Trade Commission (FTC). In addition, the FTC has written interpretive regulations.

An imported textile or the package in which it is sold is now required to bear a stamp or tag showing the country where it was manufactured or processed. The label is required on textile goods imported

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for household use. In addition, by regulation, the FTC has required the label to be "conspicuously affixed" to the product. U.S.-produced products are not required to display a country-of-origin label.

Despite these requirements, consumers are sometimes misled as to the country of origin of textile and wool products. In part, this is because the label showing the country of origin is attached inconspicuously. In addition, bundled textile products with the country of origin marked only on the bundle or package are sometimes separated once they enter the United States. Finally, the statutes concerning country-of-origin labeling are not extensive, and some confusion as to implementation and enforcement apparently exists.

Where labels are inconspicuously placed or not attached at all, foreign-made textile products are easily mistaken for American-made products, since there is no law which requires domestically produced products to be labeled with the country of origin.

Even when labels are correctly attached, consumers who purchase textile products by mail may be unable to determine a product's country of origin because they are not able to examine the item at the time or point of purchase.

Legislative History

S. 1816 was introduced by Senator Thurmond on August 4, 1983. The bill was the subject of a hearing before the Commerce Committee's Consumer Subcommittee on April 25, 1984. At the hearing, testimony was received from interested parties including Senator Thurmond, domestic textile manufacturers, textile labor unions, and a textile importer. Written testimony was submitted by the FTC and a retail trade group.

On June 13, 1984, the Committee ordered S. 1816 reported with an amendment in the nature of a substitute, and an amendment to the title.

Summary of Major Provisions

As reported, S. 1816 adds more extensive and specific labeling requirements to the Textile Fiber Products Identification Act and the Wool Products Labeling Act of 1939. The bill requires conspicuous placement of labels which contain country-of-origin information, requires both U.S. and foreign products to be labeled with the country of origin and requires labeling on product packaging, in addition to the item or items.

S. 1816 also requires limited country-of-origin disclosure in mail-order catalogues and direct-marketing literature offering textile prod-

ucts. Each printed textile product description would state that the product is made in the United States, imported, or both. If the product is imported, the specific country would not have to be identified in the catalogue description, as long as the word "imported" or other words to that effect are included.

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ESTIMATED COSTS

In accordance with paragraph 11(a) of rule XXVI of the Standing Rules of the Senate and section 403 of the Congressional Budget Act of 1974, the Committee provides the following cost estimate, prepared by the Congressional Budget Office:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, June 14, 1984.

Hon. BOB PACKWOOD,
Chairman, Committee on Commerce, Science and Transportation, U.S. Senate, Dirksen Senate Office Building, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has reviewed S. 1816, the Textile Fiber and Wool Products Identification Improvement Act, as ordered reported by the Senate Committee on Commerce, Science and Transportation, June 13, 1984.

We expect that enactment of S. 1816 would cost the Federal Government approximately $100,000 in 1985 and somewhat less in each fiscal year thereafter. No additional costs to state or local governments are expected to result from enactment of this bill.

S. 1816 would require that all textile products be labeled as to their country of origin. Mail order catalogues or sales literature would also be required to state this information. According to the Federal Trade Commission (FTC), which would be required to enforce these changes to current law, one-time costs of approximately $100,000 in fiscal year 1985 would be required to issue new regulations. Annual enforcement costs are not expected to increase significantly, unless the number of complaints increases substantially as a result of these changes.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,

RUDOLPH G. PENNER,
Director.

REGULATORY IMPACT STATEMENT

In accordance with paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the Committee provides the following evaluation of the regulatory impact of the legislation, as reported.

Although S. 1816, as reported, contains extensive country-of-origin labeling requirements, the regulatory impact on the textile industry, if the bill is enacted, should be minimal. Many of the labeling requirements reflect current FTC regulations and advisory opinions.

NUMBER OF PERSONS COVERED

The number of persons covered by country-of-origin textile and wool labeling would expand under S. 1816. Currently, only foreign textile and wool producers, and domestic producers using foreign

materials, are covered by country-of-origin labeling provisions. S. 1816 extends country-of-origin labeling to U.S. textile and wool product manufacturers. The Committee believes the additional coverage is needed to clarify the country of origin of domestically produced goods. This view was supported at the hearing on S. 1816 by representatives of the domestic textile and wool industry, the industries most affected by the labeling requirements of S. 1816.

S. 1816 also contains a provision requiring mail-order and direct mail textile retailers to disclose whether their products are "imported" or "made in the U.S.A.". Such retailers are not now required by law or regulation to include such information in their sales literature. A 1969 FTC advisory opinion (34 Fed. Reg. 14,517; FTC Advisory Opinion Digest § 15.369) held that an importer of women's panty hose was required to make a clear and conspicuous disclosure of the foreign origin of the product in all mail-order promotional material. The FTC has viewed this opinion as applicable to all mail-order imported textile retailers. Accordingly, S. 1816, as reported, imposes a new regulatory burden only on mail-order retailers of domestic textile products. The Committee believes this expanded coverage is necessary since mail-order purchasers do not otherwise have the opportunity to be apprised of a textile or wool product's country of origin at the time of purchase.

ECONOMIC IMPACT

Enactment of S. 1816 would impose some additional cost on domestic textile manufacturers, arising from the need to label each garment as made in the United States. However, these costs would be small since new tags may not be necessary and few additional words are required. All domestic industry representatives who testified at the hearing on S. 1816 were willing to assume the additional cost.

Additional costs would also be imposed on mail-order and direct mail retailers offering domestic textile products. In the Committee's opinion, such costs are justified by the desirability of disclosing a product's origin to mail-order consumers at the time of purchase.

PRIVACY

S. 1816 will have no impact on the privacy of individuals affected by the bill.

PAPERWORK

No additional reporting requirements are imposed by S. 1816.

SECTION-BY-SECTION ANALYSIS

SECTION 1—SHORT TITLE

The first section provides that this Act may be called the "Textile Fiber and Wool Products Identification Improvement Act".

SECTION 2—TEXTILE LABELING

Section 2 amends section 4 of the Textile Fiber Products Identification Act (Act of Sept. 2, 1958, Pub. L. No. 85-897, 72 Stat. 1717) (codified at 15 U.S.C. §§ 70-70k (1980)) by adding a new paragraph

that requires textile fiber products manufactured or processed in the United States to be labeled as such. The amendment applies only to goods sold in the United States and does not apply to goods not covered by the Textile Fiber Products Identification Act. This amendment is intended to be consistent with current FTC country-of-origin labeling requirements, including its standards for determining when textile products are made in the United States and may be labeled as such.

SECTION 3—TEXTILE PACKAGE LABELING

The third section amends section 4 of the Textile Fiber Products Identification Act, by adding language that requires a country-of-origin label on any textile package intended for sale to the ultimate consumer. This label would be in addition to the label or tag on the product itself. A separate tag on the package is not required if the package is transparent, and all information on the label attached to the product can be clearly read.

Section 3 exempts hosiery from the requirement that a country-of-origin label be attached, provided that: (1) the hosiery package shows the country of origin; (2) the package is intended for sale to the ultimate consumer; and (3) the information on the package is applicable to all hosiery contained in the package. The Committee adopted this exception because it understood that attachment of a country-of-origin tag to the actual hosiery product would be impractical and unsightly. The Committee intends that this exception apply only to hosiery products.

SECTION 4—MAIL ORDER DISCLOSURE AND LOCATION OF TAG

This section adds language to section 4 of the Textile Fiber Products Identification Act to require that all textile fiber product descriptions contained in mail-order catalogues and direct-marketing literature state that the textile product advertised was "made in the U.S.A.", "imported" or both.

S. 1816, as reported, requires only products produced in the United States to be identified with the specific country-of-origin in mail-order and direct-marketing literature. For textile goods not produced in the United States, the specific country of origin is not required, so long as the product's description makes clear that the product was not produced in the United States.

The Committee chose not to require foreign-produced goods to identify the specific country of origin based on testimony during the hearing on S. 1816 that some mail-order and direct marketing retailers purchase identical textile products from two or more foreign countries, and market them as the same product.

Moreover, when the catalogue or circular offering the textile product is printed, the retailer may not know which foreign country will produce the product. Because of the disclosure burden these uncertainties potentially impose on mail-order and direct-marketing retailers, the Committee concluded that identification of the specific foreign country of origin was not necessary in mail-order and direct-marketing literature. The Committee expects the specific country of origin would be identified on the textile product itself, as well as any packaging, pursuant to sections 2 and 3 above.

The Committee does not intend to imply that the exact words "made in the U.S.A." or "imported" are the only acceptable phrases in mail-order or direct-marketing literature. Other words or phrases with the same meaning may also be used. For instance, in place of the word "imported" the retailer could use "product of foreign country" or disclose the specific foreign country where the product was manufactured. The Committee intends only that mail-order and direct-marketing consumers be able to determine, at the time of purchase, whether the product was produced in the United States or imported.

The country-of-origin disclosure in mail-order and direct marketing literature should be located so that it is plainly visible to consumers and clearly explains the country of origin of each product. The Committee anticipates this can best be accomplished by including the country-of-origin disclosure with each textile product description. Some other arrangement in the catalogue or sales literature may be used, however, provided the country-of-origin disclosure is conspicuous and not misleading. With respect to both the appropriate disclosure language to be used and the location of the disclosure, the Committee expects the FTC to promulgate guidelines and provide assistance to retailers which will implement the objectives of the bill.

Section 4 states it applies to mail-order catalogues and mail-order promotional materials "used in the direct sale or direct offering for sale" of textile products. Because the Committee's intent is to provide notice of the textile products' country of origin at the time and point of purchase, mail-order catalogues and promotional material should be defined so as to include any printed material or product samples distributed or shown to consumers and from which they may purchase textile products, by mail, telephone or some other method, without examining the actual product purchased. Section 4 is not intended to apply to any nonprint advertising.

Section 4 also requires that the textile product's tag, stamp or label disclosing the country of origin be located in the most conspicuous place on the inner side of the textile product, or on the textile product. If the product has a neck, the most conspicuous place on the inside would be the center of the neck, midway between the shoulder seams. This specific language concerning textile products with necks is intended by the Committee to allow location of the country-of-origin marking at the same location now required by the United States Customs Service pursuant to the Tariff Act of 1930.

The section 4 provision concerning the most conspicuous location is not intended to change the FTC's interpretation of conspicuous location as required in the Commission's rules 15 and 16 (16 C.F.R. § 303.15-.16 (1984)) promulgated pursuant to the Textile Fiber Products Identification Act. The Committee's most conspicuous location language was included to clarify congressional intent that country-of-origin tags must be conspicuous and to indicate congressional support for FTC efforts to assure conspicuous location of these tags.

SECTION 5—WOOL LABELING

This section amends section 4 of the Wool Products Labeling Act of 1939 (Act of Oct. 14, 1940, ch. § 71, 54 Stat. 1128) (codified as amended at 15 U.S.C. §§ 68-68j), by adding a paragraph requiring all wool

products sold in the United States, and covered by the act, to be labeled with the country of origin. This section is intended to be consistent with current FTC country-of-origin labeling requirements, including its standards for determining when textile products are made in the United States and may be labeled as such.

SECTION 6—MAIL ORDER DISCLOSURE AND LOCATION OF TAG

This section adds language to section 4(a) of the Wool Products Labeling Act of 1939 to require that all wool product descriptions contained in mail-order catalogues and direct-marketing literature state that the textile product advertised was "made in the U.S.A.", "imported" or both.

The Committee intends that this section make the same substantive changes in the Wool Products Labeling Act of 1939 as those made in the Textile Fiber Products Identification Act, by section 4 of this bill. Accordingly, mail-order and direct-market retailing of wool products is to be subject to the same requirements as those imposed on textiles as explained in this report's discussion of section 4.

Section 7 also requires that the wool product's tag, stamp or label disclosing the country of origin be located in the most conspicuous place on the inner side of the wool product, or on the outside of the wool product. If the product has a neck, the bill provides the most conspicuous place on the inside would be the center of the neck, midway between the shoulder seams. The provisions in section 7 are intended to amend the substance of the Wool Products Labeling Act of 1939 in the same way section 4 of this bill amends the Textile Fiber Products Identification Act.

SECTION 7—WOOL PACKAGE LABELING

Section 7 of S. 1816 amends section 5 of the Wool Products Labeling Act of 1939, by adding language that requires a country-of-origin label on any wool product package intended for sale to the ultimate consumer. This label would be in addition to the label or tag on the product itself. A separate tag on the package is not required if the package is transparent, and all information on the label attached to the product can be clearly read.

Section 7 also excepts hosiery from the requirement that a country-of-origin label be attached provided the hosiery package shows the country of origin the package is intended for sale to the ultimate consumer; and the information on the package is applicable to all hosiery in the package. The Committee adopted this exception because it understood that the attachment of a country-of-origin tag to the actual hosiery product would be impractical. The Committee intends that this exception apply only to hosiery products.

SECTION 8—EFFECTIVE DATE

This section provides that the amendments made by S. 1816 shall be effective 90 days after the bill's enactment. The Committee intends that the bill's provisions shall apply only to products and advertising literature produced beyond 90 days after this bill is enacted.